

1 into the issue. I'm talking, again, about the 70 percent
2 of the people that would probably be relatively uninformed
3 about this, compared to many of you in the room.

4 So, certainly, as you get more interested in an
5 issue, you seek out information. You seek out all sides
6 of the issue. You're willing to spend the time and the
7 mental energy to learn the nuances of these issues, learn
8 the details of the technology.

9 All I'm saying is that, for a lot of people
10 right now, who have very busy lives, and their most
11 important problem right now is lack of time, they are
12 selective in their perception of information. When they
13 hear about a story, they would like to maybe follow up on
14 it, learn a little bit more, they would go to a source of
15 information that they would trust. Increasingly, it might
16 be on the internet, it might be an 800 number to a food
17 manufacturer; or, it may, in fact, be to a government
18 agency. They may try to learn a little bit more about it.

19 But the information seeking, I just tell you
20 now, on an issue like this, for a lot of people in this
21 country, is not going to be very sustained, and it's not
22 going to be very deep. In many ways, they're looking to
23 an organization like yours to tell them, in fact, that you
24 thought long and hard about the issue, that you made some
25 tough decisions and some tough choices on these questions.

1 But when it does come to education, I think,
2 clearly, all sides ought to be involved. I'm on a very
3 high-level committee right now of the land grant
4 university system. The land grant system in every state
5 has a college and has an extension office in every county.
6 And, in fact, there are many initiatives underway already,
7 through the land grant system, to get information out to
8 the leaders, to citizens, to consumers, to farmers, who
9 are kind of being forgotten in this whole particular round
10 of discussion so far. But, in fact, I think education has
11 to give a variety of information, has to have it out there
12 so that a person that's initially interested would then be
13 able to get it. I don't think there's going to be any
14 amount of push of information out there that is going to
15 get an uninterested person interested in the issue. But,
16 as they become interested, they want to turn somewhere
17 they can trust, and, for some people it will be the
18 organic store. They'll go in there and find the
19 information.

20 So it has to be widely available. It has to be
21 openly debated, but have to start with the premise that
22 not everybody is going to care a whole lot about this
23 issue, or as deeply, or as passionately as many of us do.
24 So we have to, in some way, not overload people. Because
25 that's the other thing I think some of you may experience:

1 information overload. And this, in fact, issue can get
2 easily lost among all the other things — much as like
3 what happened in Seattle.

4 There's an interesting analogy for you there.
5 This was the No. 1 issue for many of you in this room,
6 probably, going into WTO meetings. But as the average
7 citizen watched the news, it didn't come on the radar
8 screen very much. So that wasn't an education event.
9 That was maybe a protest event, and other things. I think
10 education is a whole lifelong process of people gaining
11 some context, gaining some insight into an issue when they
12 are interested.

13 MR. KIMBRELL: I have a very brief comment to
14 that. First of all, I couldn't disagree with you more on
15 the WTO. I think the American public finally realized
16 that we have a political issue, not an economic one. And
17 I think that's going to create a tremendous democratic
18 discussion in this country over the WTO, long overdue. So
19 I disagree with you about that.

20 But I think the irradiation issue is a very good
21 precedent for this agency. There is clearly lots of —
22 talk about a passionate issue. If you were to have a
23 panel on that, you'd probably get as much as passion as
24 you see here. People feel very passionate that
25 irradiation is either — can be an extreme health hazard,

1 or is no health hazard at all. Okay?

2 There's going to be both those sides getting
3 information out. The biotechnology industry has a lot
4 more money than the rest of us, and they're getting all
5 their information out all the time. We do the best we
6 can, as well. That's still going to happen. But that is
7 no excuse this agency not obeying the law. You obey the
8 law on irradiation. You ordered, correctly, the labeling
9 of irradiated whole foods. You had a label. You came to
10 terms with the label. That's the way this agency should
11 behave. Not the way it's behaved with genetically
12 engineered foods. That is, as I said, a regulatory
13 scandal.

14 COMMISSIONER HOLSTON: Unfortunately, we are out
15 of time for this part of the agenda. But before we turn
16 to the section of the program where we are going to hear
17 oral presentations from the members of the audience, I
18 would like to thank, very much, the members of the panel.
19 Not only those who are on the stage at the moment, but
20 those who presented earlier this morning. We have heard
21 very thoughtful discussions from each and every one of
22 you. We certainly are going to consider all of the
23 comments that we've heard, both this morning and this
24 afternoon. I expect that we will be hearing a lot more
25 from the audience after we take our break, and we will

1 also be looking at the comments that go to the docket.

2 But let just say, once more, how much we
3 appreciate the time and effort that went into your
4 presentation and thank you again very much.

5 We are now going to take a 15-minute break.
6 We're running a little bit behind schedule. We will start
7 promptly at five minutes after 3:00.

8 [Applause.]

9 [Fifteen-minute recess.]

10 COMMISSIONER HOLSTON: Could we have your
11 attention, please.

12 SCHEDULED PUBLIC PRESENTATIONS

13 COMMISSIONER HOLSTON: During this part of the
14 meeting, we are going to hear from those who have
15 requested time to address the meeting. And, as I
16 mentioned this morning, we received a very large number of
17 requests to speak at this meeting, and we want to
18 accommodate all of them. However, our time is quite
19 limited. We do have a feed going to San Francisco. We
20 must end promptly at 6:00 p.m. And, therefore, we're
21 asking each speaker to bear with us, and, as a courtesy to
22 everyone else who wants to make comments, respect the
23 two-minute time limit we have to place on the remarks of
24 each participant.

25 But, as I also emphasized this morning, we

1 encourage every one to submit full written comments to the
2 FDA docket, whose address is in your information folder.
3 This docket will remain open through January 13, 2000.

4 Also, the speakers will have an opportunity to
5 address the meeting in the order in which they arrived
6 this morning, and they received a folder with a number
7 that lists their position.

8 Bob Lake is going to moderate this portion of
9 the meeting. Please, when you come forward, would you
10 state your name and the organization, if any, which you
11 represent. Thank you.

12 Bob.

13 MR. LAKE: Just one other thing. We do have a
14 timekeeper over here. On the podium there, when you
15 start, the green light will come on. At the halfway mark
16 of one minute, the yellow light will come on; and, when
17 the two minutes is over, the red light will start to
18 flash, and I will thank you and ask the next speaker.
19 Again, we will maintain a steady line of speakers so that
20 we don't have time between speakers.

21 With that, let's get started. Go ahead sir.

22 STATEMENT OF

23 MARK LIPSON, POLICY PROGRAM DIRECTOR

24 ORGANIC FARMING RESEARCH FOUNDATION

25 MR. LIPSON: Thank you, Madame Deputy,

1 panelists. My name is Mark Lipson. I'm with the Organic
2 Farming Research Foundation. My remarks are with a title
3 borrowed from our computer system: System Failure, Abort,
4 and Retry.

5 OFRS is not categorically opposed to every use
6 of bioengineered in agriculture, but the Federal
7 Government has fundamentally failed to provide an adequate
8 regulatory regime for transgenic foods. The division of
9 responsibilities among FDA, EPA, and the USDA assures that
10 there is no comprehensive oversight governing transgenic
11 organisms released into the environment and the food
12 supply. The environmental agricultural food safety and
13 food security issues cannot be considered in isolation
14 from each other, and sound public policy has not been and
15 cannot be formulated in this fragmented system.

16 As a consequence of this policy failure, nobody
17 ultimately is in-charge except the biotech industry
18 itself, and perhaps some its university subsidiaries.
19 Unless and until a new system is put in place, a
20 moratorium on all transgenic food and agricultural
21 applications should be imposed.

22 Regarding the six specific issues posed for this
23 meeting, FDA's consultation process has failed to assure
24 public safety and it has helped to undermine confidence in
25 the products of U.S. agriculture. You should be scrapped

1 Delmer, and I'm a professor and chair of the Section of
2 Plant Biology, at the University of California at Davis.
3 I'm speaking — my comments are on behalf of myself, as a
4 plant scientist, and also on behalf of the American
5 Society of Plant Physiologists, which is a nonprofit
6 society of 5,000 plant scientists, who have elected me to
7 be their president this year.

8 So, in only two minutes, one cannot make much of
9 a point. I only want to make one point, from the point of
10 view of scientists. Many of the procedures that were used
11 to generate bioengineered plants were developed by
12 scientists like myself and my colleagues within the
13 society. And, so, we use these techniques daily in our
14 own laboratories. We understand what vectors are, what
15 promoters are. We understand the mechanisms involved.
16 And, understanding those things, the vast majority of the
17 members of our society believe that there's nothing
18 fundamentally unsafe about the directed targeting of a
19 specific gene into a plant. And it is, in fact, a more
20 directed process, as we've heard today, than many of the
21 conventional breeding processes in which many genes are
22 introduced at one time.

23 Now, lacking time to really defend that issue
24 here, I will only finish by saying that many of us plant
25 scientists realize, now, that the information gap is

1 serious, the issues are very complex, and we can't begin
2 to explain our point of view with sound bites. So, we
3 urge the press and concerned organizations to draw upon
4 us, FDA as well, because we do understand the issues
5 involved, at least in the development of the technology.
6 We'd be happy to participate in more in-depth dialogue to
7 help solve the information gap.

8 Thank you.

9 MR. LAKE: Thank you, ma'am.

10 [Applause.]

11 STATEMENT OF
12 SHARON LANINI
13 EXECUTIVE DIRECTOR

14 MONTEREY COUNTY FARM BUREAU

15 MS. LANINI: Good afternoon. My name is Sharon
16 Lanini. I'm the executive director of the Monterey County
17 Farm Bureau and a third generation California farmer. I'm
18 also a graduate of the University of California at Davis
19 in the biological sciences.

20 I'd like to address the basic questions of this
21 hearing today: The validity of FDA's current policy, as
22 it relates to agricultural biotech, and the labeling
23 issue.

24 My answer to these basic questions is that I
25 believe that the current FDA policy is science-based and

1 sound, and has worked very well for the last 5 years.
2 Therefore, it has protected the fundamental safety and
3 nutritional quality of our food and feed products to all
4 end consumers.

5 As to the question of public information on
6 biotech, adding mandatory biotech labels to ag products
7 would, at best, be innocuous and generally ignored by the
8 consumers; and, at worst, would actually mislead consumers
9 and confuse the entire issue. Which, paradoxically, is
10 what mandated labeling is supposedly trying to prevent.
11 Mandatory labeling is a bad idea.

12 Information about biotech can and should be made
13 more accessible to all interested parties. There are a
14 variety of ways that this can be done: through consumer
15 web links, hot phone lines, outreach by credible
16 university scientists, nutritionists, supplying
17 information throughout the food, fiber and feed chain.

18 The bottom line is: The United States currently
19 provides a strong safety net for agricultural biotech
20 products. Biotechnology and its ag products can literally
21 provide tremendous potential to enhance the quality of
22 life globally, with improved nutritional characteristics,
23 decreased environmental impact that literally saves lives.
24 The government regulators at FDA, USDA and EPA, who all
25 have regulatory authority over biotech products, must

1 continue to communicate and coordinate their efforts and
2 help agriculture promote the development of new biotech —

3 MR. LAKE: Thank you, ma'am.

4 MS. LANINI: — tools for our nation's most
5 important industry, agriculture.

6 Thank you.

7 MR. LAKE: Thank you, ma'am.

8 [Applause.]

9 STATEMENT OF

10 MARY WANG, Ph.D.

11 FOOD AND DRUG SCIENTIST, FOOD AND DRUG BRANCH

12 CALIFORNIA DEPARTMENT OF HEALTH SERVICES

13 SPEAKING ON BEHALF OF

14 ASSOCIATION OF FOOD AND DRUG OFFICIALS

15 DR. WANG: Good afternoon. I am Dr. Mary Wang,
16 representing AFDO, the Association of Food and Drug
17 Officials.

18 AFDO is nonprofit professional association
19 consisting of state, federal and local regulatory
20 officials. For 103 years, AFDO has actively promoted
21 uniformity and cooperation within the regulatory arena.
22 We appreciate this opportunity to present our comments.

23 AFDO has supported FDA's 1992 policy guide. It
24 applies to all developers of new plant foods where the
25 safety must be based on individual product

1 characteristics, rather than the development methods. The
2 policy guide has, since then, served as the industry's
3 gold standard. If maintaining consumer confidence in food
4 safety, oversight requires it, AFDO would support an
5 agency requirement for pre-market notification. AFDO does
6 not believe that a pre-market approval process is
7 necessary. And, with limited resources, additional
8 requirements in regulatory and enforcement activities must
9 only be in priority areas of consumer safety.

10 A food label must be truthful and not
11 misleading. When there is a safety concern, all food
12 labels must address that concern on an individual product
13 basis. When there is no identified safety concern about
14 bioengineered foods, as a class, special labeling is
15 unnecessary and should not be required. Further, requiring
16 special class labeling would place additional enforcement
17 burdens on state regulatory agencies without added health
18 protection.

19 AFDO urges the FDA to carefully consider other
20 options to better inform the consumers. FDA should
21 conduct a scientific study, one that is similar to the
22 consumer survey, that's acceptance and use of nutrition
23 labeling to determine whether new special labeling
24 regulations would benefit consumer health and safety.

25 Lastly —

1 MR. LAKE: Thank you, ma'am.

2 DR. WANG: Thank you.

3 STATEMENT OF

4 ANN M. COULSTON, M.S., R.D.

5 IMMEDIATE PAST PRESIDENT OF AMERICAN DIETETIC ASSOCIATION

6 SPEAKING ON BEHALF OF

7 CALIFORNIA DIETETIC ASSOCIATION

8 MS. COULSTON: Thank you. Good afternoon.

9 My name is Ann Coulston, and today I represent
10 the California Dietetic Association, an affiliate of the
11 American Dietetic Association. It's a group of 7,000
12 dedicated dietetic professionals.

13 We are advocates for the safe and nutritious
14 food of all. We know that the public needs accurate and
15 clear information regarding engineered food. At the same
16 time, however, we appreciate that not everything is known
17 about the hazards, if any, of these products to the
18 consumers or the environment.

19 For some time now, those who promote genetically
20 modified crops, and those who oppose them, have squared
21 off in a highly public struggle. But these individuals,
22 and often unyielding perspectives on biotechnology, can
23 mislead the public and professionals.

24 The Food and Drug Administration must take an
25 active role in educating American consumers by dispelling

1 biotechnology myths on both sides of the debate. We must
2 recognize that the biotechnology revolution is only in its
3 infancy. A few genetically modified crops and foods that
4 exist now are mere novelties compared to what will be
5 available to consumers in the imminent future. The walk
6 through the supermarket of tomorrow will be a thrilling
7 experience for those equipped to embrace and understand
8 these new products; but, for those who are unprepared for
9 and unfamiliar with the language of biotechnology, it will
10 be an alien and alienating experience.

11 As nutritionists, we believe that we are in an
12 excellent position to contribute to FDA's effort in
13 informing consumers about the potential benefits and risks
14 of foods and food products derived from biotechnology.
15 Members of the American and the California Dietetic
16 Association meet the consumer daily in schools, hospitals,
17 clinics, supermarkets, community settings, and through the
18 media.

19 We believe the U.S. consumers, accustomed to a
20 system that has served them well, have been patient as the
21 information on biotechnology comes together and has been
22 available to them. It is now time to act. This complex
23 issue requires a coordinated approach —

24 MR. LAKE: Thank you, thank you, ma'am.

25 MS. COULSTON: — directed by the FDA.

1 [Applause.]

2 MR. LAKE: Go ahead.

3 STATEMENT OF

4 DAN STEINBERG

5 MR. STEINBERG: Hi! My name is Dan Steinberg.
6 I live in San Francisco. I don't represent any particular
7 organization, but am a member of the Organic Consumers
8 Association.

9 According to the FDA policy of substantial
10 equivalence, if a genetically engineered food is
11 chemically similar to its conventional counterpart, it is
12 assumed to be safe for prolonged and widespread public
13 consumption. This policy is not supported by empirical
14 research, is obviously preferential to the biotech
15 industry, and directly contradicts the advice of FDA
16 scientists.

17 Significantly, the FDA has lied to the public
18 about information it has regarding the safety of
19 genetically engineered foods. In it's official statement
20 of policy on genetically engineered foods, the FDA states:

21 "The agency is not aware of any information
22 showing that foods derived by these methods
23 differ from other foods in any meaningful or
24 uniform way, or that, as a class, foods
25 developed by the new techniques present any

1 different or greater safety concern than foods
2 developed by traditional plant breeding."

3 The legality of the FDA policy on genetically
4 engineered foods is based on this lie. Internal FDA memos
5 disclose that several FDA scientists absolutely did not
6 agree with this assessment. For example: Dr. Linda Call,
7 at the FDA, stated in a memo to Dr. Maryanski, quote:

8 "The processes of genetic engineering and
9 traditional breeding are different; and,
10 according to the technical experts in the
11 agency, they lead to different risks. There
12 is no data that addresses the relative
13 magnitude of the risks."

14 Dr. Call also went on to state that the agency
15 was, quote, "...putting a square peg in a round hole" by
16 trying to force an ultimate conclusion there is no
17 difference between foods modified by genetic engineering
18 and foods modified by traditional breeding practices.

19 Although the FDA and the biotech industry claim
20 biotech foods have been extensively tested for safety, the
21 tests to which they refer are not empirical animal tests
22 or epidemiologically studies of humans. They are not
23 safety tests. They are simply chemical assays that do not
24 provide evidence of safety, per se. They are provide
25 measurements of the concentrations of a selected list of

1 chemicals. Nobody has ever shown that safety of
2 genetically engineered foods, or any other foods, can be
3 assured by limited chemical assays.

4 MR. LAKE: Thank you, sir.

5 [Applause.]

6 STATEMENT OF

7 CHERISA YARKIN, Ph.D.

8 ASSOCIATE DIRECTOR OF ECONOMIC ANALYSIS

9 UNIVERSITY OF CALIFORNIA BIO STAR PROJECT

10 DR. YARKIN: Hello. I'm Dr. Cherisa Yarkin.
11 I'm with the University of California Biotechnology
12 Program.

13 From an economic — I'm an economist, and, from
14 an economic standpoint, I would say that the FDA's focus
15 on product, rather than process, is absolutely
16 appropriate. In that way, you give plant breeders,
17 farmers, and others, an incentive to focus on what we care
18 about, in this instance, which is food safety. And you
19 don't constrain *a priori* the techniques that they use to
20 achieve that goal. That means that they can take
21 advantage of the advances in scientific knowledge and
22 technology over time.

23 Suppose you were to regulate the process of
24 modern biotechnology. Plant breeders would continue to
25 develop new cultivars, as needed, in agriculture. They

1 I'm the director of Legal Services for Oregon Tilth
2 Certified Organic. I was a retailer for a number of
3 years. I'm also the chairman of the Task Force on GMOs
4 for the Organic Trade Association.

5 Oregon Tilth certifies over 300 organic farms
6 and 325 processors in the United States and around the
7 world.

8 We believe strongly, with the rest of the
9 organic industry, that consumers have a right to make
10 informed food choices. The organically grown label tells
11 consumers that food is produced in compliance with the
12 Federal Organic Food Production Act of 1990. GMOs do not
13 meet the criteria set out in that act. No organic
14 certifier has ever allowed them. A large number of
15 consumers want to buy food produced without GMOs, as
16 evidenced by the 20 percent increase in our industry
17 yearly.

18 Not requiring labeling of GMO foods creates a
19 situation where consumers can only make that choice by
20 purchasing organic. Organic production requires identity
21 preservation, as you've heard, or what we call organic
22 integrity, by segregating organic crops from conventional,
23 and protecting them from contaminants. For organic
24 purposes, GMOs are contaminants.

25 Some recent testing of organic crops have shown

1 contamination by GMOs, probably from pollen drift in corn,
2 or storage with soy. This has resulted in substantial
3 economic losses. Organic farmers bear considerable
4 additional costs to prove that they don't use chemicals.

5 GMOs should be labeled and the costs of labeling
6 should be placed on those who use them.

7 MR. LAKE: Thank you.

8 MS. CLARK: Organic farmers shouldn't have to do
9 this.

10 MR. LAKE: Thank you, ma'am.

11 [Applause.]

12 MR. LAKE: Go ahead.

13 STATEMENT OF

14 DR. MARK LAPPE

15 CENTER FOR ETHICS AND TOXICS

16 DR. LAPPE: My name is Mark Lappe. I direct the
17 Center for Ethics and Toxics. In another capacity, I'm a
18 consultant to you, at the FDA, and your medical devices
19 division.

20 Now I'm not talking to you in any official
21 capacity, but I would like to talk to you and offer the
22 advice that I'm frequently asked to give to that division
23 about ethical issues relating to genetic engineering, and
24 the posture that the agency has taken on the issue of
25 labeling.

1 Specifically, the FDA has unfortunately treated
2 the issue with benign neglect. It's going to catch up
3 with. There is a groundswell of public opinion, much of
4 which you've seen in your hearings, which you've
5 generously given over the last three sessions. This issue
6 is real. The public's concerns are *bona fide*.

7 There are studies, as you will see, that are
8 beginning to demonstrate subtle differences between
9 genetically engineered and conventional crops. I've
10 submitted to the panel such a study for your review.

11 As a public health advocate, though, I have to
12 say that I've questioned the adequacy of the testing that
13 you've undertaken. I don't see that you've tackled this
14 issue with the kind of aggression it needs. When we filed
15 the Freedom of Information Act request to get all of the
16 BT studies in your files, there were none. Perhaps
17 they're at the EPA. They belong in your files. Ingestion
18 of potentially contaminated food is squarely within your
19 domain. Thank you.

20 [Applause.]

21 MR. LAKE: Thank you, sir.

22 STATEMENT OF

23 SUE MARKLAND DAY

24 PRESIDENT, BAY AREA BIOSCIENCE CENTER

25 MS. MARKLAND DAY: Good afternoon. I'm Sue

1 Markland Day, the president of the Bay Area Bioscience
2 Center, and a former staffer to the House of
3 Representatives Agriculture Committee. I was a specialist
4 in family farms and initiated the first Organic Farming
5 Act.

6 The Bay Area Bioscience Center is a 9-year-old,
7 independent nonprofit, headquartered in San Francisco..
8 The BABC's mission is to strengthen Northern California's
9 climate for bioscience research, development and
10 commercialization through public education outreach. Our
11 region is home to more than 120,000 professionals, not
12 including those in education, medical care, who rely on
13 life sciences for their livelihood.

14 As to the question of labeling, the consumer
15 certainly has a right to know what is in his or her food.
16 Replacing the words "genetically engineered," "genetically
17 modified," of "bioengineered" on a label does not provide
18 content information. Just labeling of food, as to its
19 development process, does not inform the consumer that a
20 grain, fruit, or vegetable has improved nutritional
21 values, such as contains 100 percent of one daily
22 allowance of Vitamin A, or is grown without the use of
23 chemical pesticides.

24 Labeling for content may make sense. But
25 labeling for process technology will not make food

1 labeling — will make food labeling incomprehensible and
2 misleading. Consumers have a right to understand the
3 content of food, but modification to the seed, or
4 otherwise, whether genetically altered or not, is not the
5 key. Nutrition and safety is. Labeling of food, if
6 genetically modified at all, does not inform the consumer
7 that FDA considers the food product and that the USDA, EPA
8 review for safety and ecological impact was acceptable.
9 This is the type of information I, for one, would find
10 most useful.

11 In conclusion, food product labels can provide
12 an excellent opportunity to inform the public about food
13 content and the role of FDA, USDA, and EPA in food safety.
14 Improved nutritional content is another already modified
15 by FDA as appropriate for labeling.

16 MR. LAKE: Thank you, ma'am.

17 [Applause.]

18 STATEMENT OF

19 IRVIN J. METTLER, Ph.D.

20 MANGER, TECHNOLOGY ACQUISITION AND CONTRACTS

21 SEMINIS VEGETABLE SEED, INC.

22 DR. METTLER: Good afternoon. My name is Irvin
23 Mettler, and I'm representing Seminis Vegetable Seed
24 Company.

25 Seminis Vegetable Seed Company is a leading

1 vegetable seed company active in worldwide markets. We
2 produce over 60 different crop species, and over 2,000
3 different varieties of seeds in our market.

4 As a seed company, we basically sell genetics or
5 new combinations of genes, and are committed to providing
6 our growers with improved agronomic characteristics, such
7 as insect, disease, stress and increased yield; and, for
8 the consumer, improved quality traits, such as color,
9 taste and nutrition.

10 Currently, using what can be called classical
11 breeding methods, each year we release hundreds of new
12 varieties of vegetable crops for sale. Each of these have
13 hundreds, perhaps maybe even thousands, of new
14 combinations of genes. And many of these also have new
15 organoleptic properties, nutritional qualities, et cetera,
16 which some this afternoon mentioned may require labeling.
17 Based on our experiences, the existing FDA guidelines have
18 been transparent, effective, and have functioned to assure
19 the safety of our food supply.

20 On a final note, I would just like to relate my
21 own personal experience observing the safety of
22 genetically modified corn plants that have been engineered
23 to be resistant to insects, using the BT gene. In 1995, I
24 visited a field trial in Northern Iowa, where the
25 conventional corn was compared against the BT corn. This

1 was a year of high insect pressure; and, when we went down
2 the row of conventional corn, every ear had been chewed,
3 the kernels had been damaged. Even worse, had been
4 infected —

5 MR. LAKE: Thank you, sir.

6 STATEMENT OF

7 PETER M. ROSSETT, Ph.D.

8 EXECUTIVE DIRECTOR, FOOD FIRST

9 THE INSTITUTE FOR FOOD & DEVELOPMENT POLICY

10 DR. ROSSETT: My name is Peter Rosset. I have a
11 Ph.D. in biology from the University of Michigan. I'm the
12 executive director of the Institute for Food & Development
13 Policy.

14 I have submitted written comments, which I will
15 not read, but which are titled: "Ten Reasons Why
16 Biotechnology Will Not Insure Food Security, Protect the
17 Environment, or Reduce Poverty." They summarize
18 scientific research, put together by our institute,
19 basically rebutting the two principle public relations
20 claims of the industry, as to why we need these foods and
21 these crops so rapidly, which are, (1) that they will help
22 feed the hungry; and (2) protect the environment. We show
23 quite conclusively that both of these claims rest on false
24 assumptions.

25 However, since there is limited time, what I

1 would do is: If there are any members of the media who
2 would like a copy of the written statement, I have them
3 available. Therefore, as I said before, I will not read
4 them. Instead, I would like to take the minute remaining
5 to me to make two comments.

6 The first is addressed to those of you who have
7 read the *New York Times* in the last few days. In that
8 sense, I would like to state, for the record, that I have
9 not been paid by Monsanto, or any public relations firm
10 retained by any biotechnology company to appear here. Nor
11 have my transportation or meals been paid by any
12 biotechnology company. And I think it's important to
13 state that up front.

14 The second point I'd like to make is about the
15 nature of public hearings. Allowing only 1 hour and 50
16 minutes at the end of a long day, after most of the media
17 have left, for the public to speak, makes a mockery of our
18 democratic process, and a mockery of the phrase "public
19 hearings." I think the FDA —

20 [Applause.]

21 — has the democratic duty to engage in a real
22 discourse, a real discourse, with members of the public.

23 Thank you.

24 [Applause.]

25 MR. LAKE: Thank you, sir.

1 //

2 STATEMENT OF

3 BETH BURROWS

4 PRESIDENT/DIRECTOR, THE EDMUNDS INSTITUTE

5 MS. BURROWS: I'm Beth Burrows, president and
6 director of The Edmunds Institute, a public interest,
7 nonprofit organization, dedicated to research and
8 education about environment and technology.

9 This year, I attended biosafety discussions in
10 Cartagena, Columbia; Vienna, Austria; New Delhi, India;
11 Burlington, Vermont; Bryansk, Russia; and Seattle,
12 Washington, to name a few of the venues. And I think it
13 is safe to tell you what you must undoubtedly already
14 know, notably that people the world over are concerned
15 about the safety of genetically engineered food. They do
16 not believe you, and they will avoid, by any means
17 necessary, to avoid having such food shoved down their
18 throats. I advise you to read their lips.

19 In answer to the question of whether FDA
20 policies have served the public, I, as representative of
21 my Institute, can only say: No, no, very sadly, no; they
22 have not.

23 The policies, that have put unlabeled
24 genetically engineered food that has not been stringently
25 and independently tested onto the world's plates, are

1 policies that have led to a loss of confidence in the
2 quality and safety of our food and the agricultures that
3 produce it. To a loss of confidence in FDA's willingness
4 to regulate. To a loss of confidence in FDA's
5 independence and integrity. To a loss of confidence in
6 FDA's ability to differentiate absence of evidence of
7 hazard from absence of evidence of looking for hazards.
8 To a loss of confidence in FDA's ability to trace future
9 public health problems back to novel foods that have been
10 allowed onto our marketplaces unlabeled. To a loss of
11 confidence in FDA's ability to serve the common good in
12 the face of encumbering a promising industry. To a loss
13 of confidence in FDA's ability to understand that,
14 although science may inform the decision making, it should
15 not be the sole decision maker. And finally, to a loss of
16 confidence in FDA's ability to understand what is meant by
17 genuine public dialogue, or how to conduct a respectful
18 public hearing.

19 Thank you.

20 MR. LAKE: Thank you, ma'am.

21 [Applause.]

22 STATEMENT OF
23 CLAIRE CUMMINGS, ESQ.
24 KPFA RADIO REPORTER

25 MS. CUMMINGS: My name is Claire Cummings. I'm

1 here representing just myself.

2 I have about 30 years experience in agriculture
3 and food. I used to be a USDA attorney and a former
4 special assistant U.S. Attorney, and I'm here mostly in my
5 capacity as a journalist covering food and farming issues,
6 to talk about the question of how your communicating with
7 the public. You've made it really difficult to attend
8 this hearing and to speak to you, and I think that speaks
9 for itself in many ways. It's been really difficult for a
10 lot of people to be here.

11 I think one of the reasons I used to be a part
12 of the Federal Government was because I really believed in
13 public service. I want to appeal to that part of
14 yourselves that also may believe in public service, and to
15 understand that the proper role of the government is to
16 stand between the merchants of greed, like Monsanto, and a
17 trusting public. If you're feeling that you have trouble
18 communicating with the public, it's because you're not
19 acting with integrity in these issues. You're acting as
20 if, you're acting as if you're interested in the public,
21 instead of acting in the public interest.

22 I also want to say that my other personal view
23 is that there are moral implications to biotechnology, and
24 I want to represent that. I gave a sermon recently here
25 in Oakland on the moral implications of genetic

1 engineering called the "Comodification of the Sacred,"
2 which is what I think we're having, we're dealing with
3 here. And I don't think I'm alone in holding that 6
4 billion years of evolution, that species line that's being
5 violated by recombinant DNA technology is a violation of
6 something sacred. And I would like to invoke that, as
7 well.

8 I think the public deserved to be respected in
9 their feelings on these issues. Thank you.

10 [Applause.]

11 MR. LAKE: Thank you, ma'am.

12 STATEMENT OF

13 PEGGY G. LEMAUX

14 UC COOPERATIVE EXTENSION SPECIALIST

15 MS. LEMAUX: My name is Peggy Lemaux. I'm a
16 cooperative extension specialist at the University of
17 California. Although professionally, I represent an
18 important public institution, I also grew up on a farm, am
19 a consumer and a mother. I'm concerned about the nature
20 and the safety of our food.

21 Since the 1970s, I've been engaged in the fields
22 of classical genetics and genetic engineering. As such, I
23 think I'm able to evaluate the scientific risks involved
24 in the use of these new technologies. Most individuals
25 don't have this background. I don't have the background

1 to evaluate the vagaries of the stock market.

2 Because many individuals aren't able to evaluate
3 the new food products being developed with classical and
4 modern genetic technologies, regulatory agencies have that
5 responsibility. They must make decisions about risk based
6 on sound science. Scientists have the responsibility to
7 provide adequate, additional, independent assessments of
8 risk through carefully controlled, peer-reviewed studies.
9 As consumers, we can then use that information to help us
10 make decisions about our own personal safety, which we
11 define as acceptable risk.

12 In the popular press, many articles discussing
13 foods developed through biotechnology have focused on
14 possible or imagined risks. Should these foods developed
15 using the new genetic technologies be labeled? For food
16 safety reasons, as a practicing scientist, I'd say no. The
17 foods developed using the new tools are not zero risk, but
18 they're not inherently more risky than foods developed
19 through classical genetics. For consumer choice reasons,
20 again, I would say no. U.S. consumers look to food labels
21 to provide information on the composition and attributes
22 of foods, not to the details of agricultural or
23 manufacturing processes used to produce it.

24 Labeling a fresh fruit or vegetable would be
25 fairly simple, although it really wouldn't provide the

1 consumer with much information. With a processed food,
2 like ketchup, which might contain 6 different varieties,
3 each with its own new gene, labeling becomes complicated.
4 As a scientist, I know what would be required to monitor
5 that ketchup for those genes. I personally can't support
6 a system that would raise the price of food significantly
7 for everyone.

8 MR. LAKE: Thank you, ma'am.

9 [Applause.]

10 STATEMENT OF

11 JAMES DIAMOND, M.D.

12 BIOTECHNOLOGY TASK FORCE, SIERRA CLUB

13 DR. DIAMOND: Hello. I'm Jim Diamond,
14 representing Sierra Club, our nation's largest grass roots
15 conservation group. I'm a pediatrician.

16 I've admired the work of the FDA in regulating
17 drugs. Transgenic agriculture has gone from zero to 80
18 million acres in 5 years. This is astonishing. Like all
19 new technologies, it involves risks, some foreseeable,
20 others not. We could draw parallels to the introduction
21 of the automobile. Car crashes were foreseeable, smog
22 wasn't. We speak, of course, about foreseeable risks, but
23 unknown risks are very important, also. A reminder that
24 decisions based on sound science can be wrong. We need
25 some humility. We need to know that our knowledge base is

1 always changing and a caution is the key element of
2 judgment.

3 Two minutes isn't enough. Speaking as a
4 consumer, I'd like to know what I'm buying and eating.
5 Speaking as a physician, I know that they're public health
6 risks involved in having pesticides and
7 antibiotic-resistant genes engineered into our food.
8 Speaking as an environmentalist, I know that taking genes
9 from one species and putting them into different, entirely
10 different, species is not substantially equivalent to
11 anything we've ever done before.

12 The agency's position that the public has
13 nothing to worry about isn't science. Science calls
14 things by name and takes a good hard look. The Sierra
15 Club is asking for just that, clear labels, so we know
16 what we're dealing with. Good science, not all done by
17 industry and not protected by trade secrecy provisions.
18 We call for informative labels, such as: This corn
19 contains a bacterial gene coating for an insectidial
20 antitoxin. Human health effects are unknown.

21 On behalf of the Sierra Club, thank you very
22 much.

23 MR. KIMBRELL: Thank you, sir.

24 [Applause.]

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2 STATEMENT OF

3 THERESA SELFA

4 RURAL SOCIOLOGIST

5 MS. SELFA: Hi! My name is Theresa Selfa, and
6 I'm here just as a consumer.

7 I would like to express my concern that foods,
8 which contain GMOs need to be labeled. As a conscientious
9 consumer, a mother, and a rural sociologist, who works on
10 food, agriculture and community development issues in the
11 U.S., as well as in developing countries, I would like to
12 have this information so that I can make choices about the
13 food I eat. I'm concerned that GMO foods have not been
14 sufficiently tested to determine both human and
15 environmental effects.

16 I am concerned that genetically engineered foods
17 are being promoted by the same few corporations, which now
18 completely dominate the food industry. This consolidation
19 has not only created power for monopolies, but has also
20 been linked to economic declines in the farm economy,
21 particularly for small farmers.

22 Finally, while these corporations are promoting
23 genetically engineered as an essential solution to world
24 hunger, I see just the opposite. Right now, farmers in
25 Washington State, which is where I live, and across the

1 U.S., are suffering from an overproduction crisis, leading
2 to low prices. Many are going out of business. Farmers
3 can't even cover their costs of production, and the
4 numbers of hungry people in the U.S. and around the world
5 are increasing. So this obviously is not a production
6 problem, but a distribution problem. And I don't see how
7 giving increased power to a few corporations will do
8 anything to solve this problem.

9 Thank you.

10 [Applause.]

11 MR. LAKE: Thank you, ma'am.

12 STATEMENT OF

13 RICHARD L. MATTEIS

14 EXECUTIVE VICE PRESIDENT, CALIFORNIA SEED ASSOCIATION

15 CALIFORNIA GRAIN AND FEED ASSOCIATION

16 MR. MATTEIS: I'm Richard Matteis. I'm the
17 executive vice president of the California Seed
18 Association and the California Grain and Feed Association.
19 I wear both hats.

20 I'd like to commend the FDA for holding this
21 meeting here today, and the process I think is working
22 well. We do support the current regulatory program, as
23 is. It's clear from the testimony today that there's many
24 benefits from the production of foods through
25 biotechnology.

1 With regard to the consultation process, we
2 support the voluntary process that is in place now, and
3 feel that it is working. That is evidenced by the fact
4 that there is not one shread of evidence of any single
5 food safety problem occurring from the use of
6 biotechnology to produce foods; and, therefore, it is
7 working.

8 We see companies involved in producing seed
9 which have been selecting for traits for hundreds of
10 years. They've used various means to do that:
11 cross-breeding, hybridization, and now this newest
12 technology, biotechnology. Some years hence there may be
13 some other techniques that we use to do that. But I can
14 assure you that the companies involved are intent on
15 producing a product that is safe.

16 Let's not confuse the fact, either, that the
17 seeds that are produced through biotechnology are not the
18 ultimate foods. Those are a different thing. We heard a
19 smoke-screen argument about things being patented,
20 therefore they're different. The process may be
21 different, the seed may be different; but the end food
22 product is substantially equivalent.

23 With regard to labeling, we are opposed to
24 mandatory labeling of these products. We feel, as there
25 are consumer benefits that are promoted, other than the

1 production benefits we have now, that those companies
2 selling those products will want to clearly get that
3 information to the public so that they can take advantage
4 of that intended market. The market will drive that
5 issue.

6 Just pointing on my Grain and Feed hat for a
7 second, we have spent millions of dollars in this state
8 alone to protect our milk supply, and other food products,
9 from contamination by aflatoxin. There is very real
10 evidence that, through this technology, we're going to be
11 able to reduce the microtoxins that occur in our feed
12 products.

13 I think FDA does have a role to play in
14 providing information to the public so that there not
15 confused.

16 MR. LAKE: Thank you, sir.

17 [Applause.]

18 STATEMENT OF

19 SIMON HARRIS

20 BIODEMOCRACY CAMPAIGN

21 MR. HARRIS: HI! My name is Simon Harris. I'm
22 speaking on behalf of Biodemocracy.

23 I don't really have any comments, but I would
24 like to propose a few questions to the panel.

25 How can a federal agency be simultaneously

1 responsible for regulating and promoting a technology,
2 genetic engineering, which has the potential to devastate
3 ecosystems, cause massive public health epidemics, and
4 ruin the livelihoods of farmers in rural communities
5 worldwide?

6 Why are you holding these hearings in 1999, a
7 year in which tens of thousands — sorry — tens of
8 millions of acres GE crops are planted, instead of five
9 years ago before the first genetically engineered foods,
10 diary products derived from Monsanto's genetically
11 engineered bovine growth hormone were surreptitiously
12 slipped into our food supply?

13 Global agriculture now produces a 50 percent
14 surplus in terms of global food needs, so why should we
15 believe that the alleged yield increases of genetically
16 engineered crops will do anything to address the problems
17 of food distribution and poor people's access to food?

18 How can these genetically engineered crops feed
19 the hungry people of Asia, Africa, and Latin America when
20 most of them are fed to livestock to support the developed
21 world's insatiable appetite for meat products?

22 How can you consider the insertion of a fish
23 gene into a tomato, or human genes into pigs, to be
24 substantially equivalent to selecting plants each year
25 which grow taller or bear more fruit than their

1 counterparts?

2 How can we believe that a company like Monsanto,
3 who makes the world's largest selling herbicide, is
4 actually interested in reducing chemical use by farmers?

5 Why are FDA's officials time and time again
6 found to have financial conflict of interest with the
7 very companies whose products they're approving?

8 Why are the results of independent scientists
9 discounted as inaccurate while the findings of those on
10 agribusiness payrolls, like today's demonstration by he
11 so-called Coalition of Concerned Scientists, considered to
12 be unquestionable scientific fact?

13 Why should a few companies, whose abysmal past
14 track records concerning the environment, human health and
15 corporate accountability be allowed to control the world's
16 seed and food supply?

17 I would like to conclude by asking my first
18 question again: How can a federal agency be
19 simultaneously responsible for both regulating and
20 promoting a technology, genetic engineering, which has the
21 potential to devastate ecosystems, cause massive public
22 health epidemics —

23 MR. LAKE: Thank you, sir.

24 MR. HARRIS: — and ruin the livelihoods of the
25 farmers and communities worldwide?

1 [Applause.]

2 MR. LAKE: Go ahead.

3 STATEMENT OF

4 KATE BURROUGHS

5 HARMONY FARM SUPPLY

6 MS. BURROUGHS: Hi! My name is Kate Burroughs.
7 I'm co-owner of Harmony Farm Supply. Thank you for
8 holding the public hearing to take input regarding
9 genetically engineered food.

10 As a consumer, I demand the right to choose what
11 kind of food I am eating. At a bare minimum, the FDA must
12 make it mandatory immediately that all foods that contain
13 any GE, GMO ingredients be clearly labeled, regardless of
14 whether it is a major or minor ingredient. As part of my
15 moral and spiritual beliefs, it is critical that I not eat
16 bioengineered foods as currently available in the
17 marketplace.

18 The current products of the bioengineers break
19 two of Ghandi's seven deadly sins: Commerce without
20 morality, and science without humanity. How dare FDA
21 determine GE foods are comparable to non-bioengineered
22 foods when there have been no long-term feeding studies
23 done on any GE crops. The short-term studies show there
24 can be increased allergens in GE foods, that antibiotic
25 resistant marker genes were routinely used in GE crops and

1 increase the risks humans becoming resistant to
2 antibiotics. And some GE crops, like GE potatoes, have
3 been shown to be poisonous to mammals, resulting in vital
4 organ damage and immune system damage.

5 There is also the issue of food quality and
6 nutrition in GE foods. Several studies show reduced
7 nutritional value in GE foods. I refuse to be a guinea
8 pig or lower my standard of eating so the bioengineers can
9 recoup their billions of dollars of investment.

10 FDA must require stringent pre-market animal and
11 human studies to ascertain whether new allergens or toxins
12 are present in genetically engineered foods. Voluntary
13 compliance is not enough. Bioengineers are the same
14 companies that brought dioxin-contaminated Agent Orange
15 herbicide and other environmental disasters. They don't
16 exactly have a sterling track record for voluntarily
17 removing unsafe products from the marketplace. The
18 overall problem is a lack of respect for the complexity of
19 life and food webs.

20 As a certified organic farmer, I am furious that
21 GE crops are being allowed to genetically pollute other
22 crops being grown within wind distance of GE crops. The
23 potential for the creation of superweeds and superbugs is
24 imminent, and I don't see EPA or FDA making any attempts
25 to stop it. Do the right thing and make GE products

1 labeled.

2 MR. LAKE: Thank you, ma'am.

3 [Applause.]

4 STATEMENT OF
5 RITA MITCHELL, PRESIDENT
6 CALIFORNIA NUTRITION COUNCIL
7 UNIVERSITY OF CALIFORNIA

8 MS. MITCHELL: My name is Rita Mitchell. I am a
9 registered dietitian and president of the California
10 Nutrition Council, a nonprofit organization of nutrition
11 professionals. CNC members have expertise in influencing
12 nutrition policy in California, and in communicating
13 nutrition information to the public.

14 Few issues in recent years have sparked more
15 interest or passion than bioengineered foods. CNC
16 acknowledges that some consumers are concerned about the
17 safety of bioengineered foods. We encourage consumers to
18 study the issues carefully and consider sound science when
19 making food decisions. We believe that consumers have a
20 right to information so they can make informed choices.

21 New plant production and processing techniques
22 have provided society with tools to alleviate pressing
23 problems in human health and environmental stewardship.
24 Food biotechnology has the ability to provide benefits for
25 both consumers and producers. For example: It has helped

1 enhance the quality, shelf life, nutritional value and
2 variety of foods available.

3 CNC encourages FDA's continued commitment to
4 insure the safety and regulatory concerns that are
5 addressed in the production and marketing of bioengineered
6 foods. We support current regulatory policy, which
7 requires labeling when new products are significantly
8 different in safety or nutritional quality.

9 CNC members believe the communication and public
10 education about the use of bioengineering is critical. We
11 encourage the media and others who provide information to
12 consumers to do so in a responsible manner. Present facts
13 supported by sound science, rather than emotion.
14 Communicate potential benefits, as well as potential
15 risks. Address consumer concerns.

16 We encourage the FDA to fund educational
17 outreach, as well as consumer research on beliefs,
18 attitudes and behaviors. CNC supports scientific research
19 on appropriate uses of biotechnology, and encourages
20 consumers to educate themselves on all aspects of this
21 topic.

22 We applaud the FDA for providing this
23 opportunity to speak out publicly. Thank you for your
24 attention..

25 MR. LAKE: Thank you, ma'am.

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STATEMENT OF

MARTINA MC GLOUGHLIN

DIRECTOR, BIOTECHNOLOGY PROGRAMS

UNIVERSITY OF CALIFORNIA, DAVIS

MS. MC GLOUGHLIN: My name is Martina
McGloughlin. I'm the director of the Biotechnology
Program at UC at Davis. I grew up on a small farm, and
I'm not paid by any company to be here today.

I believe the regulatory oversight, above all,
needs to be science based. An august group of scientists
and the National Research Council determined that, as
molecular methods are more specific, users of these
methods will be more certain about the traits they
introduce into plants. Greater certainty means greater
precision and safety. The subtly altered products are now
placed and are being put through more thorough testing
than any conventional food ever has been subjected to.
Many scientists who worked in the past on crop
improvements, using much less precise methods of crop
breeding, mutation-induced breeding, a wide species cross,
did not go through the same type of scrutiny or inquiry.

Ironically, many of our daily staples would be
banned if subjected to today's rigorous standards.
Potatoes and tomatoes contain toxic glycoalkaloids
(phonetic); kidney beans contain phytohemagglutinin

1 (phonetic) which are poisonous if undercooked. Organic
2 growers use copper sulfate and animal feces, yet none of
3 these are labeled.

4 Comments by Dr. Regal on misinformation should
5 apply to himself on unexpected effects. Salmon growth
6 hormone is expressed in the liver because it is under
7 control of the metallitinen (phonetic) promoter, which is
8 expressed on the liver, so the surprise would be if it
9 wasn't expressed there. On BT pollen, truckloads of
10 information was provided to the FDA before the Cornell
11 Study. There was nothing new there, except that forced
12 feeding Monarchs is not — is still less hazardous than
13 using traditional chemicals. However, evolving
14 technologies, including transformation will eliminate
15 pollen expression, removing not only Monarch hazards, but
16 also gene flow of concern to organic growers.

17 Site specific targeting will address Dr. Fagan's
18 concern or random integration, which, by the way, also is
19 caused using traditional methods. Although, I suspect Dr.
20 Fagan's real concern is creating a market for his company.

21 The only conclusive scientific point —

22 [Applause.]

23 I'm sorry.

24 The only conclusive scientific point that Dr.
25 Putze's (phonetic) study on lectins and potatoes proved

1 was that rats do not like eating raw potatoes. Scientists

2 —

3 MR. LAKE: Thank, thank, thank you, ma'am.

4 [Applause.]

5 STATEMENT OF

6 PHILLIP LA ROCCA

7 PRESIDENT, BOARD OF DIRECTORS

8 CALIFORNIA CERTIFIED ORGANIC FARMERS

9 MR. LA ROCCA: Excuse me, I'm losing my voice.

10 My name is Phillip LaRocca —

11 MR. LAKE: If I may ask the audience, we are
12 very squeezed for time. And, you know, I would like the
13 next speaker to be able to go ahead and get started;
14 otherwise, we won't finish. Thank you for your ...

15 Go ahead.

16 MR. LA ROCCA: My name is Phillip LaRocca. I've
17 been in the organic industry for 30 years. I farm 200
18 acres of certified organic wine grapes. Have a certified
19 organic winery, and I have 350 head of sheep under
20 certification. I am the president of the Board of
21 Directors for the California Certified Organic Farmers.

22 Thank you for this opportunity to speak here.

23 I would just like to mention, in terms of
24 labeling, that, as a certified organic grower, we are
25 forced to label our products. There hasn't been any

1 controversy over the detrimental effects of organic
2 growing to the environment, to the healthy individual;
3 yet, we are forced to do it. It just seems ironic to me
4 that we have countries objecting to GMO products that they
5 don't have to label.

6 Also, in regards to labeling, most of our 1,100
7 farmers and processors are proud to put the CCF seal on
8 the label. It allows the consumer to make that decision
9 if they want to buy something that has been grown
10 organically or not. We saw, in the case of the bovine
11 growth hormone, not only did they not want to label that,
12 but they passed a law saying that people that weren't
13 using it couldn't label it. That shows fear, not pride.

14 In terms of sound science, my family has been
15 farming for years. I remember 40 years ago, when they
16 were told sound science gave them DDT, and there was
17 nothing to worry about DDT. Forty years later, we're
18 still seeing residue of DDT in our soil. We also are
19 still seeing the effects that it had on the environment.
20 We never had to use bees to pollinate; now we do.

21 Also, in terms of — and this is a touchy one
22 here — in terms of biological pollution, I actually make
23 a warning to you: The USDA received 265,000 citizens
24 telling the government that they did not want GMOs in
25 organic agriculture. If this happens, watch out. We are

1 a \$6 billion industry. You will be affecting the
2 livelihood of a lot of people in that industry. In
3 California and throughout the country, it is against the
4 law to breathe second-hand smoke. We don't want our
5 organic crops polluted by GMO materials.

6 Thank you very much.

7 [Applause.]

8 MR. LAKE: Thank you, sir.

9 STATEMENT OF
10 NELL NEWMAN
11 FOUNDER, NEWMAN'S OWN ORGANICS
12 DIVISION OF NEWMAN'S OWN

13 MS. NEWMAN: My name is Nell Newman, and I'm the
14 founder of Newman's Own Organic, a division of Newman's
15 Own. Our division has grown tenfold in 7 years. We'll
16 gross approximately \$8 million this year. It has a line
17 of products which range from 80 to 100 percent organic.

18 Due to time constraints, I will limit my
19 comments today to question 1, in section A: Has the FDA's
20 consultation practice achieved its intended purpose of
21 resolving all safety and regulatory issues?

22 No, it has not. Because it did not address the
23 effect of biotech on the safety of the nation's organic
24 food supply.

25 Over the past year, the extensive planting of

1 GMO crops in the U.S. has become the bane of my existence
2 and threatens my livelihood in the organic food industry.
3 Our customers expect that products meet the national
4 organic standards, which does not allow GMOs. The
5 potential contamination of organic crops has created a
6 nightmare for those of us trying to insure the integrity
7 of our organic ingredients. We are now having to consider
8 the cost of testing all of our ingredients, which could
9 potentially be contaminated at some point in the growing
10 or manufacturing process.

11 For a company which donated all of its profits
12 to charity, it means that I'm now wasting my charity
13 dollars trying to figure out whether or not Monsanto has
14 cross-contaminated any of my raw ingredients. This year,
15 one of my corn growers spent over \$16,000 testing for GMOs
16 to insure that her crop had not been cross-pollinated.

17 So, if you broaden your scope of the definition
18 of safety, you see that the FDA's consultation process has
19 not protected the safety of organic farmers.

20 I believe that testing and labeling is
21 unfortunately now going to be a necessity. I also believe
22 that a complete moritorium is needed to evaluate all the
23 concerns you've heard here today. My question to the FDA
24 is: In the coming years, what safe haven will I have to
25 plant my organic corn crops in, and who will cover the

1 liability and losses that are bound to occur?

2 Thank you.

3 MR. LAKE: Thank you, ma'am.

4 [Applause.]

5 STATEMENT OF

6 KENT J. BRADFORD, DIRECTOR

7 SEED BIOTECHNOLOGY CENTER

8 UNIVERSITY OF CALIFORNIA, DAVIS

9 MR. BRADFORD: My name is Kent J. Bradford. I'm
10 a professor of Vegetable Crops and director of the Seed
11 Biotechnology Center at the University of California at
12 Davis. As a plant biologist, I'd like to address a couple
13 of the issues that I've heard today.

14 We've heard that it's a violation of the sacred
15 to mix species. I'd like to say that every single tomato
16 plant that's grown commercially in California — and we
17 grow about 95 percent of the processing tomatoes that
18 everyone eats in their pizzas and tomato sauce, a very
19 large fraction of the fresh market tomatoes — everyone of
20 those carries genes that have been transferred from other
21 species. If we did not have those disease resistant genes
22 that have been transferred from those species, we would
23 not be growing any of those tomatoes in California. I
24 would venture to say that likely, even the organic
25 growers, who are growing tomatoes in this state, are using

1 varieties that contain those genes. They've been
2 transferred by nonrecombinant DNA techniques, but they are
3 still transferred from other species.

4 A couple of other issues that I'd like to just
5 mention.

6 I heard today about the pollen contamination of
7 organic crops. I'd just like to mention that the use of
8 biotechnology has not increased contamination; that is:
9 It has not made pollen fly farther or grain handling
10 procedures be any different than they were before. All
11 it's allowed us to know is the level of contamination that
12 must already be there from nonorganic adjacent crops, or
13 other types of crops. The only difference is that we can
14 now find it because you can test for the DNA and you know
15 that you have a contaminant. So I believe if the
16 contamination is the real issue, then, we need — and the
17 real concern is the label of being pure, and therefore,
18 not contaminated with anything that's not organic, the
19 issue is still there, and it's not being created by
20 biotechnology. It's just been able to be discovered by
21 biotechnology.

22 The last thing I'd say is that I think that we
23 don't now label, require labeling on the final product,
24 just indicate the variety from which it was produced. And
25 I don't believe that we should in the future. I think

1 that the FDA's current guidelines are rational, they're
2 science-based, they're safe and they're effective. I urge
3 the agency to maintain its current position with respect
4 to food labeling.

5 MR. LAKE: Thank you, sir.

6 [Applause.]

7 STATEMENT OF
8 SYLVIA DEMAREST, ESQ.

9 DEMAREST, SMITH, JONES, GUINTA & MOORE

10 MS. DEMAREST: Good afternoon. My name is
11 Sylvia Demarest. I'm an attorney in private practice in
12 Dallas, Texas. I appear before this panel as a private
13 citizen.

14 A recent poll by a public relations firm found
15 that 62 percent of Americans were unaware that genetically
16 modified foods were already being marketed. More shocking
17 are the figures showing the extensive penetration of the
18 food supply, including the presence of GMO organisms in 60
19 to 80 percent of all processed foods. This has occurred
20 without the knowledge or the consent of the American
21 people. Surveys have shown that 80 to 90 percent of all
22 Americans support the labeling of genetically modified
23 organisms. Yet, these foods are not labeled and industry
24 is opposed to labeling.

25 So, who then can vouchsafe the safety of the

1 American food supply? The biotech companies deny that
2 they should have to guarantee the safety of biotech food.
3 One company, Monsanto, stated: "Our interest is in
4 selling as much of it as possible. Assuring its safety is
5 the FDA's job." Yet, the FDA has certainly not served as
6 a regulator on this issue. Instead, the FDA has allowed
7 itself to become seriously compromised by its relationship
8 with the biotech industry.

9 What has emerged is a sophisticated circle game,
10 where the regulatory ball is passed from the FDA to the
11 EPA to the USDA without any agency assuming final
12 responsibility. All that the FDA requires is voluntary
13 consultation. This process is fundamentally flawed and it
14 violates the Food, Drug and Cosmetic Act. This Act
15 incorporates the precautionary principle. Meaning that
16 food additives are presumed unsafe until proven safe.
17 These additives have never been tested, much less proven
18 safe.

19 Further, there is no scientific consensus
20 supporting the FDA's regulatory approach even among FDA
21 scientists. Surely this is not acceptable. The FDA
22 claims to be the nation's foremost consumer protection
23 agency. Is this true?

24 MR. LAKE: Thank you, ma'am.

25 [Applause.]

1 STATEMENT OF
2 MELODI NELSON

3 VICE PRESIDENT, TERRA PRIMA, INC.

4 MS. NELSON: Good afternoon. Thank you for this
5 opportunity to be heard.

6 I'm Melodi Nelson, coowner of a small business
7 in Hudson, Wisconsin. We export certified organic
8 agricultural commodities to Japan, as well as a line of
9 certified organic tortilla chips to Europe.

10 In December of 1998, we were forced to issue a
11 recall of over 87,000 bags of organic tortilla chips that
12 were discovered to have been made with organic corn that
13 was accidentally contaminated by wind-borne pollen from
14 neighboring genetically modified corn. This recall, as
15 well as the continued loss of the sales, for my company,
16 had been a financial disaster.

17 There are many reasons to be skeptical of the
18 so-called benefits of this technology, not the least of
19 which, in many regards, to genetically modified life
20 forms, is: Once mistakes are made, it may not be possible
21 to ever undo these mistakes.

22 But I've traveled from Wisconsin to talk about
23 choice, the choice of all of us in the organic industry
24 have made. Whether we're farmers, retailers, commodity
25 brokers, or consumers, we have made the choice to raise,

1 eat and support organic sustainable agriculture. This
2 does not include genetically modified organisms. We have
3 the right to make this decision. We have the right to not
4 have our farms contaminated and our livelihoods taken away
5 from us. We have the right to know what we choose to eat
6 and feed our children. We have the right and obligation
7 to be skeptical. What is at stake is the safety and the
8 security of our food source around the world.

9 There are currently no regulations for labeling,
10 no way to trace health effects, no way to protect
11 consumers, as well as their right to make informed
12 decisions. There's no required testing to show that these
13 organisms are safe. No rigorous, no independent study, no
14 comprehensive testing requirement. No one can tell us
15 what the consequences of releasing these genetically
16 modified organisms in nature will be. I believe the risks
17 far outweigh any unproven potential benefits.

18 I would request that all government agencies
19 rescind the registration and the use of genetically
20 modified organisms in agriculture production.

21 Thank you.

22 MR. LAKE: Thank you, ma'am.

23 [Applause.]

24 //

25 //

1 STATEMENT OF

2 JORGE VALLE, GRADUATE STUDENT

3 MR. VALLE: Hello! My name is Jorge Valle. I'm
4 a consumer. I represent only myself and my family, and I
5 don't have any special affiliations.

6 To start with, the idea of modified food is not
7 natural. A strawberry, for example, were not meant to
8 have fish or other strange types of genes in them. In
9 addition, just because scientists haven't yet found any
10 harm in GMOs doesn't mean there are neutral to our health,
11 with no side effects.

12 In the past, scientists also thought all the
13 technological inventions were great. What happens to the
14 environment, CFCs, for example. Until after a few decades
15 of widespread use have passed when it was discovered that
16 they were, in fact, very harmful.

17 The point is: We just don't know, for sure, if
18 GMOs are harmless or harmful. Either way, nature did not
19 make such strange mixtures of genes and was probably for a
20 reason.

21 Lastly, even if some people don't mind eating
22 it, neither I nor my family should be forced upon GMOs.
23 Consumers should be given the choice of whether eating
24 GMOs or not. Genetically modified food products should be
25 clearly labeled as millions of consumers also in the

1 European Union are demanding.

2 I don't see why I should be forced to eat
3 cabbage with scorpion genes. I just want a choice. So,
4 please, just give me a choice.

5 MR. LAKE: Thank you, sir.

6 [Applause.]

7 STATEMENT OF

8 DR. NEAL GUTTERSON

9 MANAGING DIRECTOR OF RESEARCH,

10 DNA PLANT TECHNOLOGY CORPORATION

11 DR. GUTTERSON: Good afternoon. My name is Neal
12 Gutterson. I'm the managing director of research at DNA
13 Plant Technology Corporation, located right here in
14 Oakland, California.

15 On behalf of my company, I'd like to offer the
16 following comments:

17 First, from a standpoint of insuring safety of
18 the food supply, we support fully your 1992 statement of
19 policy regulating foods produced using biotechnology. We
20 urge you to continue with this policy, which is
21 appropriately science and safety based, not processed
22 based. The scientific risk assessment principles endorsed
23 by the National Academy of Sciences, and other world
24 experts, provide a solid foundation guiding us in the
25 development of food products.

1 We utilize the consultation process established
2 in 1992 to assure the safety of a long shelf life tomato
3 variety developed to reduce shipping and post-harvest
4 damage, thereby providing a better product for the
5 consumer. Your staff reviewed our package of information
6 on the nature of the genetic modification, relevant
7 nutrients, and the levels of naturally occurring
8 toxicants, which demonstrated that this
9 biotechnology-derived tomato variety is substantially
10 equivalent to other commercial tomato varieties.

11 We have recently returned from another
12 consultation in which we provided FDA staff with
13 information on products in a very early stage of
14 development. We believe this process works well to insure
15 the safety of our country's food supply.

16 Second, we believe that consumer confidence in
17 the FDA and the regulatory process that governs
18 biotechnology-derived foods is essential to the continued
19 adoption of this extraordinarily useful, and eventually
20 vital technology.

21 DNAP, both individually and together with our
22 industry colleagues, has urged you and other federal
23 regulatory agencies to better explain your role in
24 assuring food safety. Education, as to the process you
25 employ, is truly the key. We see these public sessions as

1 one clear example of your commitment to assuring that the
2 public's confidence in this food supply parallels the
3 safety of the food supply itself. We urge you to continue
4 in this outreach to the public.

5 MR. LAKE: Thank you, sir.

6 [Applause.]

7 STATEMENT OF

8 ELISA ODABASHIAN

9 SENIOR POLICY CONSULTANT, CONSUMERS UNION

10 WEST COAST REGIONAL OFFICE

11 MS. ODABASHIAN: MY name is Elisa Odabashian.
12 I'm with Consumers Union, a nonprofit publisher of
13 *Consumer Reports Magazine*.

14 Consumers Union has long maintained that
15 consumers have a right to know what goes into the foods
16 their buying and eating. We urge the FDA to require both
17 safety testing and labeling on genetically engineered
18 foods.

19 While to date there has been little scientific
20 evidence that genetically engineered foods presently on
21 the market are unsafe, this does not mean that the FDA and
22 industry can say, with impunity, that biotech foods are
23 absolutely safe. There is still much to be learned about
24 the long-term impact of genetically modified foods on
25 human health and the environment.

1 A good example of this is the use of synthetic
2 bovine growth hormone, or RBGH, in the production of milk,
3 on which human health tests have never been done. Not
4 only does the drug cause numerous health problems to cows,
5 thereby requiring intense use of antibiotics, which can
6 lead to increased resistance in farm-borne bacteria that
7 affects humans; but a number of international scientific
8 bodies have called for further research on the impact of
9 RBGH on humans. And the drug is banned in both Canada and
10 the European Union.

11 The recent demonstrations in Seattle at the
12 World Trade Organization Meeting is a seering example of
13 how it never pays to keep information from the public, nor
14 to turn a deaf ear to consumers' expressed desires, and
15 unwillingness by government and industry to label
16 genetically engineered foods is born of fear, not of
17 confidence. Fear that, if consumers were fully informed,
18 they would draw incorrect conclusions and spend their
19 money on products not containing GE-modified organisms.

20 In a democracy, it is fundamentally not the
21 place of government or industry to dictate what
22 information consumers should or should not be given, or to
23 determine in advance how consumers will interpret that
24 information. The only way to inspire consumer confidence
25 in genetically engineered foods is through full

1 disclosure. In other words, through mandatory labeling.

2 MR. LAKE: Thank you, ma'am.

3 [Applause.]

4 STATEMENT OF

5 REBECCA SPECTOR, PROGRAM COORDINATOR

6 MOTHERS & OTHERS FOR A LIVABLE PLANET

7 MS. SPECTOR: My name is Rebecca Spector, and
8 I'm program coordinator for Mothers & Others for a Livable
9 Planet, here in San Francisco.

10 Mothers & Others is a national nonprofit
11 consumer education and advocacy organization, with over
12 30,000 nationwide. Our mission is to promote consumer
13 choices that are safe and sustainable for current and
14 future generations. One of our primary goals is to
15 educate consumers about safe and sustainable food and
16 production practices, and increase consumer access to
17 these foods.

18 We've come a long way in working toward these
19 goals, as the tremendous demand for organic and natural
20 foods has increased exponentially over recent years.
21 Consumers not only want safe and sustainable foods, but
22 they also have the right to adequately tested and labeled
23 food, including those that have been genetically
24 engineered.

25 The introduction of genetically engineered foods

1 into the environment and our supermarkets has been very
2 rapid. GE foods are being introduced without thorough
3 testing of long-term impacts on human health and the
4 environment. Some preliminary tests on GE crops show
5 reasons for concern and further testing. We should invoke
6 the precautionary principle and hold back on introduction
7 of these new technologies until they are better
8 understood. As the November 26 issue of the journal
9 *Science* points out:

10 "The evidence so far hasn't pinpointed any
11 specific problems, but also can't dispel the
12 doubts. Further testing could help dispel any
13 doubts."

14 We know from experience with pesticides that
15 once hazards enter the ecosystem and our bodies, they are
16 nearly impossible to eliminate and can result to harm to
17 human and environmental health for generations. DDT, for
18 example, is still found in human breast milk, as well as
19 the fat of other mammals. It would be unwise to repeat
20 our mistakes and allow an inadequately tested technology
21 to proliferate on our farms and in our foods without proof
22 of their safety.

23 Consumers have the right to know what's in their
24 food and how it is produced. Consumers also have the
25 right to expect government agencies and businesses to

1 adequately test the impact of food ingredients on human
2 health and the environment before they are introduced into
3 farms and into the marketplace.

4 Thank you.

5 MR. LAKE: Thank you, ma'am.

6 [Applause.]

7 STATEMENT OF

8 ANGELO SACERDOTE

9 MR. SACERDOTE: Good afternoon. My name is
10 Angelo Sacerdote. I have a production company called
11 Wholesome Goodness Production, and I'm working on a
12 documentary on the subject. I'm speaking today as a
13 concerned citizen.

14 From the beginning, the thrust of FDA policy has
15 been to foster the growth of the U.S. biotech industry,
16 rather than to critically examine this radical new
17 technology. We have been hearing the biotech industry
18 applaud the FDA's science-based policy, the FDA's policy
19 regarding substantially altered crops should be
20 substantially equivalent to their conventionally bred
21 counterparts, and also claims that these foods are
22 generally regarded as safe by most scientists. Even
23 scientists within the FDA dispute these claims. The fact
24 is there is no consensus among scientists regarding the
25 safety of this food.

1 I'm with the Organic Materials Review Institute, a
2 nonprofit group which works on policy for inputs on
3 ingredients for organic crop production and processed
4 foods. Our 29 subscribing certification organizations and
5 state program represent over 6,500 certified organic
6 producers and food processors.

7 As you've heard already, the organic food
8 industry has a commitment to not allow genetically
9 engineered organisms, or their derivatives, into our food.
10 Those of us who serve that industry are faced with a huge
11 challenge of determining which ingredients in processing
12 aids may come from a GMO source. Even those ingredients
13 that are present in small amounts are in widespread use
14 and very important in organic food processing.

15 We're in favor of labeling, both primary and
16 incidental ingredients and processing aids, as well as all
17 seeds and the products of crops produced from those seeds.
18 We feel that much more thorough study is needed of the
19 whole system involved in agriculture and food production
20 before these products should be just allowed everywhere in
21 our food supply.

22 At a minimum, the following groups of
23 ingredients should be labeled if they contain the products
24 of bioengineered: Enzymes, amino acids, cultures of all
25 micro organisms from yeast to bacteria, starches made from

1 genetically engineered crops, gums, citric acids,
2 sweeteners, oils, vitamins, and weigh and dairy
3 derivatives.

4 Finally, I'm a consumer who is so highly
5 allergic to soy beans and peanuts that my life would be
6 threatened by eating the smallest amount. I am highly
7 dependent on reading food labels to stay alive. I could
8 not tolerate a gene from a soy bean being bred into a crop
9 that was not labeled on a product. Therefore, my life is
10 in your hands on this issues.

11 MR. LAKE: Thank you, ma'am.

12 [Applause.]

13 STATEMENT OF
14 AMIGO CANTISANO
15 ORGANIC AGRICULTURE ADVISORS

16 MR. CANTISANO: I'm Amigo Cantisano, and I'm
17 president of Organic Ag Advisors. I'm an organic farmer
18 for 25 years and organic farming advisor to 160 farmers,
19 producing more than 200,000 acres of a wide variety of
20 organic and transitional crops.

21 I am here today to strongly protest the use of
22 genetic engineering in agriculture, especially its
23 negative effects on organic farming. Scientific research
24 has already shown that BT-engineered crops can have severe
25 negative impacts on beneficial insects, such as lady bugs

1 and lace wings. These organisms are very important to
2 organic farmers. Reductions on their life span will
3 threaten our crops.

4 BT-enhanced crops take extremely long periods to
5 breakdown in the soil, causing significant soil ecological
6 changes. The microbial activity of the soil is crucial to
7 organic farming. BT has been successfully used by organic
8 farmers as a nontoxic pest control for more than 30 years.
9 However, due to continued exposure to the BT toxin in GMO
10 crops, insects have rapidly developed resistance to this
11 useful bacteria. This has already happened in the
12 southern U.S. wherever BT cotton has been extensively
13 planted. We will soon lose the effectiveness of BT, one
14 of the most important pest control used on organic farms.

15 The widespread use of bovine growth hormone in
16 the dairy industry results in RBGH residues in the dairy
17 manure, some of which is being used by organic farmers to
18 make compost. Contamination of composting feed stocks by
19 GMO crops raises economic and ecological concerns for
20 organic farmers and consumers.

21 We demand the outright ban of all currently
22 allowed GE crops, a 3-year moratorium on the release of
23 anymore genetically engineered plants, and mandatory,
24 full-disclosure labeling for all crops and products
25 containing GMOs. The FDA must act immediately to protect

1 the integrity of the food system and minimize
2 contamination of organic and other farms. Thorough
3 long-term, independent scientific studies of the health
4 and ecological effects of GMO crops must be completed
5 before anymore GMO crops are allowed in agriculture.

6 Organic farming can provide high quality and
7 high yields, which meets the needs of our society.

8 Thank you.

9 MR. LAKE: Thank you, sir.

10 [Applause.]

11 STATEMENT OF

12 JO ANN BAUMGARTNER

13 NEPTUNE FARMS

14 MS. BAUMGARTNER: My name is Jo Ann Baumgartner,
15 and I'm half owner of Neptune Farms.

16 I've farmed organically on the California
17 Central Coast for 15 years. My customers have always
18 expected the highest integrity from our products. The
19 drift from unregulated GE crops is causing genetic
20 pollution. Organic and conventional non-GE farmers should
21 not have to suffer to accommodate these Frankenstein
22 foods.

23 Not only should GE products be labeled on the
24 shelf, but they should also be labeled in the field, so
25 that non-GE growers will know if we should think twice

1 before we plant a corn crop next to our neighbors.

2 The other aspect I want to address is bovine
3 growth hormone issues.

4 BGH increases milk production at the expense of
5 animals and our health. Cows are more likely to have
6 infections; and, therefore, require more antibiotics.
7 IDF-1, a product formed in the BGH milk, has been linked
8 to higher rates of cancer. What is really astounding is
9 that, if the producer, who is giving a daily shot to one
10 of his cows does not realize that this animal has quit
11 producing, the hormone will act as growth promoter and the
12 cow will grow to twice its size. What do you think the
13 producer does with this animal? It ends up as hamburger.

14 BGH promotes unhealthy, unregulated and inhumane
15 practices. Testing should be done on all BGH dairy cows
16 destined to be slaughtered and eaten, and BGH milk and
17 meat should be labeled.

18 We demand integrity from you, our government
19 officials. Don't tell us GE crops are the same as our
20 historically grown foods. We know they are not.

21 Thank you.

22 [Applause.]

23 MR. LAKE: Thank you, ma'am.

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1 STATEMENT OF
2 JOSEPH PANETTA
3 CEO/PRESIDENT BIOCOM

4 MR. PANETTA: Good afternoon, ladies and
5 gentlemen. MY name is Joe Panetta. I'm president and CEO
6 of BIOCOM, San Diego, a regional association in Southern
7 California, representing some 350 companies engaged in the
8 application of biotechnology in agriculture, life
9 sciences, medical devices and pharmaceuticals.

10 I'm also the former chairman of the
11 Biotechnology Committee at the American Crop Protection
12 Association in which I represented my former company,
13 Micogen. At Micogen, I was responsible for leading the
14 regulatory affairs program. And at Micogen, we received
15 the first approvals of BT corn in the United States and
16 other countries around the world.

17 I've had the opportunity to work on six
18 continents, with regulatory officials in the approval of
19 BT corn. I can assure you that the fact that we have
20 stronger support in this country, in the surveys that are
21 done of the public on biotechnology, that are testimony to
22 the fact that the FDA has been open, not just in holding
23 these hearings, but holding public comment periods in
24 1992, with the publication of your policy on novel foods,
25 and going all the way back to 1986 in the publication of

1 the coordinated framework for biotechnology.

2 Both BIOCUM and ACPA believe that the FDA's
3 current regulatory framework regarding crops improved
4 through biotechnology provide adequate and appropriate
5 protection for consumers for the following reasons:

6 It's based on scientific fact, rather than on
7 science fiction.

8 It's concerned with the nature of the product
9 and not the process by which the product was first
10 produced.

11 It recognizes that genetic techniques of today
12 are not something holding new, but a logical extension of
13 centuries old, incremental progressions of agricultural
14 technology.

15 It's cognizant of the reality and not the
16 supposition that genetic techniques being utilized today
17 in agriculture are more precise; and, thus, more
18 predictable than the predominant techniques of 20 or 30
19 years ago.

20 It focuses on benefitting the consumer, rather
21 than rewarding those who can merely the most noise.

22 It's generally accepted by the broad scientific
23 community that, in terms of safety of the consumer, foods
24 improved through biotechnology are no different than other
25 foods produced through so-called traditional methods.

1 MR. LAKE: Thank you, sir.

2 STATEMENT OF

3 BRUCE MARTIN

4 MR. MARTIN: My name is Bruce Martin.

5 Part of my education, health education, is to
6 encourage them to eat healthy foods, preferably organic.
7 But this population, a lot of them have limited income,
8 are on SSI. Preparing food, sometimes they're limited
9 physically, too. They have to prepared foods at the
10 store, convenience foods, which are presently not labeled
11 as to the substances.

12 This morning's seminar, he showed a graphic
13 showing that the majority of the present GMOs that are on
14 the, that are being produced, are patented for resistance
15 to herbicides and pesticides. There's been numerous
16 studies showing that these are leftover. There are
17 residues in fruits, vegetables that can be washed out.
18 This population, with the compromised immune systems, are
19 very sensitive to any chemicals in their food.

20 I'm urging that there will be, there should be,
21 labeling for this population that is at high-risk for the
22 increased amount of residues in the food because of
23 genetic modification.

24 Thank you.

25 MR. KIMBRELL: Thank you, sir.

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STATEMENT OF
KATI BUEHLER
DIRECTOR, ENVIRONMENTAL & REGULATORY AFFAIRS
WESTERN CROP PROTECTION ASSOCIATION

MS. BUEHLER: Good afternoon. I'm Kati Buehler, with the Western Crop Protection Association in Sacramento. My comments will focus on three of the public information issues posed in the *Federal Register Notice*.

No. 1. FDA's consultation process. WCPA supports the regulatory framework provided by the USDA, EPA, and FDA, and believes it fully examines food safety risks and concerns. We also have confidence in the systems ability to evolve as scientific advancements are achieved.

No. 2. FDA's current labeling policy. WCPA strongly supports FDA's existing science-based labeling policy. This means we support the labeling of genetically-improved foods, whether it's a significant compositional change, where the food is nutritionally different from its traditional counterpart, or where a potential allergen has been introduced. The FDA labeling policy also allows for voluntary labeling statements that are truthful and not misleading.

No. 3. Providing additional information. Through focus groups and telephone surveys, consumers are

1 telling the U.S. food industry that they are able to
2 obtain information about food biotechnology from the news
3 media, internet, food companies and academic experts.
4 These sources can provide far more useful information than
5 just labeling. In fact, a new survey from the
6 International Food Informational Council found that 81
7 percent of American consumers agree that it would be
8 better for food manufacturers, the government, health
9 professionals, and others, to provide more details through
10 toll free phone numbers, brochures and web sites.
11 However, much more can be done to provide information to
12 the public.

13 We urge the FDA to increase public outreach
14 efforts with more attention paid specifically on
15 familiarizing consumers with the regulatory system
16 currently in place.

17 Thank you very much.

18 MR. LAKE: Thank you, ma'am.

19 [Applause.]

20 STATEMENT OF

21 ALANA SMITH

22 DIRECTOR, RESEARCH AND DEVELOPMENT

23 HARRINGTON INVESTMENTS, INC.

24 MS. SMITH: My name is Alana Smith. I'm the
25 director of Research and Development at Harrington

1 Investments. We're a registered investment advisors,
2 managing \$130 million.

3 We have a fiduciary responsibility, and we are
4 concerned with the potential legal and financial liability
5 of the companies that manufacture, distribute, or use
6 genetically engineered ingredients.

7 Unfortunately, the FDA, and other U.S.
8 regulatory agencies, have failed the American public by
9 not requiring comprehensive, prerelease safety testing;
10 or, at the very minimum, requiring companies to label
11 GMOs. This leaves food safety in question, and food,
12 seed, and agricultural chemical companies, grocery stores
13 and Federal Government legally and financially liable for
14 health, safety and environmental effects that may result
15 from premature release of GMOs.

16 The burden of proof should be on the agencies of
17 the government to prove, beyond a reasonable doubt, that
18 food products released to the public for consumption meet
19 maximum health and safety standards that are safe for the
20 environment and the human consumption. Currently, the
21 public must prove that a product endangers the public
22 safety before the government acts to remove the product
23 from the stores' shelves.

24 On October 27, Harrington Investments filed a
25 shareholder resolution with seven companies: Coca Cola,

1 Pepsi, General Mills, Quaker Oats, Sara Lee, Proctor &
2 Gamble, McDonalds. We co-filed with Monsanto and DuPont.
3 We've asked that they remove genetically modified
4 ingredients until further long-term safety testing can be
5 shown that these products are safe for human and animal
6 consumption, and the environment. We also asked that, in
7 the interim, these companies label the products as such.

8 Our clients are not alone. There are many other
9 concerns. Shareholders, stakeholders, environmental
10 groups that are currently in dialogue with corporate
11 management to protect the public from potential dangers of
12 these foods. This is not enough. We call upon the FDA to
13 act immediately.

14 Thank you.

15 MR. LAKE: Thank you, ma'am.

16 [Applause.]

17 STATEMENT OF

18 DR. ROY L. FUCHS

19 DIRECTOR OF REGULATORY SCIENCE

20 MONSANTO CO.

21 DR. FUCHS: Good afternoon. I'm Roy Fuchs, from
22 Monsanto.

23 I've been responsible for the food, feed and
24 environmental safety of Monsanto's plant biotechnology
25 products for the past 10 years. I'll briefly address an

1 important topic, which was raised during the FDA meeting
2 in Washington, D. C.

3 A panelist questioned whether the plant biotech
4 products on the market met FDA's food safety standard of
5 reasonable certainty of no harm. Plant biotech products,
6 which have completed FDA's consultation process, have
7 clearly met this well established food safety standard.

8 Monsanto has established that our biotech
9 products are compositionally and nutritionally equivalent
10 to the parental varieties from which these products were
11 derived, and show that the proteins expressed for the
12 introduced DNA are safe for humans, animals and the
13 environment. The food safety assessment for these
14 products is based on extensive testing following the
15 guidance provided by FDA, by key international food safety
16 organizations, which include the World Health
17 Organization, the United Nation's Food and Agricultural
18 Organization, International Life Sciences Institute, and
19 by regulatory agencies around the world. For example:
20 Over 1,800 analyses were conducted with Round-Up Ready Soy
21 Beans to establish their safety.

22 The proteins produced from the inserted DNA have
23 a long history of safe use. For example: The BT family
24 of proteins, which confer insect protection, were
25 subjected to extensive short- and long-term toxicology

1 testing prior to their approval for use in microbial BT
2 products. These products have been used safely
3 commercially for almost 40 years. The protein used to
4 confer tolerance to Round-Up herbicide is a member of a
5 protein family which occurs in every plant, every
6 bacterium, and every yeast, all of which have been
7 consumed safely for centuries. In addition, detailed
8 safety studies were conducted with each of these proteins
9 to confirm their safety.

10 The conclusion that Round-Up Ready soy beans are
11 as safe and nutritious as other soy beans has been
12 confirmed by regulatory approvals in Europe, Canada,
13 Japan, Switzerland, Argentina, and numerous countries
14 around the world. As a developer of these products, we're
15 committed to insuring their safety.

16 MR. LAKE: Thank you, sir.

17 DR. FUCHS: Thank you.

18 [Applause.]

19 STATEMENT OF

20 AMY BRICKER

21 PROJECT DIRECTOR, CENTER FOR FOOD SAFETY

22 MS. BRICKER: Hi! My name is Amy Bricker. I'm
23 a project director at the Center for Food Safety.

24 I'd like to thank the FDA for inviting us to
25 give our feelings on genetically engineered foods today.

1 However, the FDA is already keenly aware of the public's
2 interest and views on this issue.

3 In 1992, the agency received thousands of public
4 comments on the 1992 food policy. In 1993, it also
5 received thousands of letters during a comment period
6 specifically concerning the labeling issue. Again, in
7 1994, the FDA heard public input at a scientific
8 conference on allergens and genetically engineered foods.
9 And most recently, as the FDA is well aware, over 275,000
10 members of the public commented on these issues to the
11 USDA during it's proposed national organic rulemaking.
12 During all of these comment periods, the public
13 overwhelmingly supported three things:

- 14 1. Mandatory premarket safety testing of
15 genetically engineered foods;
- 16 2. Mandatory environmental review of these
17 foods; and
- 18 3. Mandatory labeling.

19 Despite recognition of these public sentiments,
20 the FDA has refused even to respond to these comments. As
21 as a result of the FDA continued refusal to acknowledge
22 public concerns on this issue, our organization was
23 compelled to file a lawsuit against the FDA. This lawsuit
24 is consistent with the public's comments and also
25 establishes the FDA's legal requirements to take action

1 under the Federal Food, Drug and Cosmetic Act.

2 It is unfortunate that the FDA has forced the
3 public to litigate on a matter of such critical importance
4 and consumer concern. A decision on this lawsuit could be
5 handed down by the United States District Court, for the
6 District of Columbia, by the end of this year. Regardless
7 of this decision coming forward from the court, it is
8 about time for the FDA to start acting like a servant of
9 the American public and not a slave of the industry.

10 Thank you.

11 [Applause.]

12 MR. KIMBRELL: Thank you, ma'am.

13 MR. HEINBERG: I'm Richard Heinberg, a core
14 faculty member at New College of California, where I teach
15 courses on ecology and human culture.

16 I'm also a journalist. Three years ago, a
17 publisher contracted me to research and write a book on
18 the moral impact of biotechnology. My research led me to
19 conclusions critical of both the biotech industry and the
20 FDA. The dispute about biotech foods is often portrayed
21 as good science, versus public hysteria. What I learned
22 dramatically contradicts that view.

23 Recently, peer-reviewed journals have published
24 showing damaging health and environmental effects from
25 genetically engineered crops, as well as reductions in

1 nutritional quality. These findings should surprise no
2 one. Because the new technology is inherently risky.
3 Indeed, my research led me to conclude that the hazards
4 are so novel and great that the requirements for the
5 testing of genetically engineered foods should be far more
6 rigorous than those for standard pharmaceuticals or
7 chemical food additives. Instead, in defiance of its own
8 scientists' warnings in memos — initially suppressed but
9 now available on the internet — the FDA has required
10 little or no testing, not even the labeling of genetically
11 modified foods. Many ethicists I interviewed regard this
12 not just as a failure of the FDA's mandate to protect
13 American citizens, but as an outrage against democracy
14 itself.

15 If anyone believes biotech foods are safe, I
16 would not prevent them from eating them. But that
17 millions should be caused to eat poorly tested genetically
18 engineered foods without their knowledge or consent is
19 unconscionable. Perhaps conflicts of interest involving
20 agency officials are to blame.

21 In any case, history may not look kindly on the
22 FDA's failure in this instance to offer adequate
23 protection to the American people when it could have done
24 much more. I urge you to begin to reverse this perilous
25 course of inaction by requiring the labeling of all

1 genetically engineered foods and food ingredients.

2 Thank you.

3 [Applause.]

4 MR. LAKE: Thank you, sir.

5 STATEMENT OF

6 DANIEL H. JOHNSON, JR., M.D.

7 CLEARVIEW MEDICAL IMAGING

8 DR. JOHNSON: Good afternoon, and thank you very
9 much for giving me the opportunity to speak and share my
10 thoughts on food biotechnology.

11 My name is Daniel Johnson. I'm a practicing
12 physician in a high-tech specialty, in a suburb of New
13 Orleans, Louisiana. I'm a former president of both the
14 American Medical Association and the World Medical
15 Association.

16 I'm pleased to be here today with a physician
17 travel grant from the International Food Information
18 Council. But I'm speaking as an individual who has become
19 very interested in the subject before you. My interest
20 derives from the fact that, every day in my practice, I
21 use biotechnology to do what I consider almost miraculous
22 things to deliver care to ordinary people.

23 The developments that I use in my practice would
24 never have possible if we had not recognized that the
25 benefits of biotechnology outweigh the risks — and the

1 risks are there. And food biotechnology is simply the
2 application of biotechnology in food production. And it,
3 too, may have risks.

4 In my view, the FDA's role is to manage that
5 risk. But I suggest that the benefits far outweigh those
6 risks. In time, food biotechnology may enhance a
7 physician's ability to use food to improve a patient's
8 health. But if we abandon this technology because of what
9 might go wrong, these valuable tools will never make it
10 into the hands of physicians and their patients.

11 I know that safety is a tremendous concern to
12 those who are not as enthusiastic about science and
13 technology as I am. But my endorsement of biotechnology
14 is built on my faith in the FDA's existing review process.
15 I believe it has served us well and will continue to do
16 so.

17 I'd like to just close by making the observation
18 that I disagree with the comments that some have made that
19 this is not an open and fair process. On the contrary,
20 I've had the opportunity to have been engaged in public
21 discourse for many, many years now. I think this is an
22 extraordinary opportunity for you to listen to a very
23 diverse group of comments. The panels you had today were
24 very balanced. The comments you've heard today I found
25 very fascinating and across the whole spectrum of input.

1 I comment you for holding this hearing.

2 MR. LAKE: Thank you, sir.

3 [Applause.]

4 STATEMENT OF
5 DAVE HENSON, EXECUTIVE DIRECTOR
6 OCCIDENTAL ARTS & ECOLOGY CENTER

7 MR. HENSON: Greetings! My name is Dave Henson.
8 I'm the executive director of the Occidental Arts &
9 Ecology Center up in Sonoma County. We're an organic farm
10 research and education center. We focus on biodiversity
11 and food crop seeds.

12 I'm a citizen, first; a consumer, sometimes.
13 That's important, because it's a democratic process. It's
14 not about consumers and corporations. This is the first
15 step in a better democratic discussion. Thank you for
16 holding it.

17 I hope you all had a chance at lunch to see the
18 spontaneous outbreak of democracy that occurred outside.
19 Many, many hundreds of people could not be in here because
20 this room size was the limit, and these amazingly tiny
21 seats were aggravating to sit in all day. I encourage
22 you, at the next democratic discussion, to have a big hall
23 and invite everybody to listen. Because there could have
24 been a lot of learning on all sides.

25 [Applause.]

1 On this question of material differences and
2 substantial equivalence in GE products, transpecies
3 genetic engineering is a quantum leap in breeding
4 technologies, with no scale equivalent in natural
5 evolution. Let's be clear: It's disingenuous, at best,
6 to suggest, as some of the corporate operatives and Ms.
7 Huttner insisted on, that transpecies transferred genes is
8 the same as traditional plant breeding. It is not. It
9 insults our intelligence.

10 Others have spoken well on many issues. I want
11 to address context, for a second.

12 We are an agrarian species. A hundred thousand
13 years of agriculture have given birth to civilization.
14 Modern food crops are the results of collective invention
15 and conscious selection of millions of farmers all over
16 the world. This co-evolved relationship between cultivator
17 and cultivar is deeply sacred and should invoke great
18 humility on the part of you all and us when we imagine
19 changing it forever. And changing to genetic engineering
20 is forever. We cannot go back.

21 It's the height of arrogance of the so-called
22 life science corporations and the U.S. Government to seek
23 to patent, privatize and commodify and lease back to the
24 world's farmers the collective commonwealth of our
25 ancestors. I beg you to take this seriously and think

1 deeply. This moment in history is a big one, and we're
2 not — it's going to be remembered in history as the time
3 we decided.

4 Thank you.

5 [Applause.]

6 MR. LAKE: Thank you, sir.

7 STATEMENT OF
8 PAUL BETTENCOURT
9 COTTON GROWER

10 MR. BETTENCOURT: Good afternoon. My name is
11 Paul Bettencourt. I'm a cotton grower from Fresno County,
12 down in the San Joaquin Valley. Thanks for coming out to
13 California.

14 In 1999, we planted our first biotech cotton. I
15 planted BT cotton, 12 sacks of it, just to see how it
16 worked, and it works great. You could see down to the row
17 where our BT cotton was, separate from our other cotton.
18 And, you know, farmers are hammered about being, you know,
19 careful for the environment. Here, I had a product that
20 saved me at least two applications of pesticide for the
21 same amount of bug control, and we're getting criticized
22 for it. You know, that part of it, I don't quite
23 understand.

24 As a farmer, you know, I am committed absolutely
25 to consumers and the environment, and that's why I like

1 the BT cotton, for the environment. I understand the
2 concerns of the consumers. Nothing that I do, as a
3 farmer, is above question.

4 As to the question of whether I'm beholden to
5 Monsanto, those guys are a pain in the neck to work with
6 on this seed. You don't know how many hoops you got to
7 jump through to get a couple sacks of seed.

8 I'd like to leave you with a question: Why
9 should we change the current regulations because they
10 work? What we have here is not an additive to the crop,
11 but we have a new varieties.

12 Philosophically, you're being asked to perform
13 an impossibility. You can't prove a negative if we take
14 this to the extreme. My concern is that tools that will
15 help me, as a farmer, care for the environment and be
16 productive will be taken away by playing on people's fears
17 needlessly. I urge the FDA to maintain its current
18 policy.

19 Thank you very much.

20 [Applause.]

21 MR. LAKE: Thank you, sir.

22 STATEMENT OF
23 SKIP SPITZER, CHAIR
24 SANTA CRUZ ACTION NETWORK

25 MR. SPITZER: Good afternoon. I'm Skip Spitzer.

1 I'm the chair of SCAN, the Santa Cruz Action Network. For
2 about 20 years, SCAN has been in the business of helping
3 consumers organize and participate in environmental and
4 public health issues.

5 I appreciate the dilemma the FDA faces. I can
6 see, internally, you're addressing the issue of agency
7 performance and statutory compliance. I can see the
8 obvious context of limited resources that you have to work
9 with. And I can see you're emphasis on cooperation with
10 so-called stakeholders, many of whom have very different
11 perspectives.

12 One source of crystal-clear direction you can
13 rely on, however, is your own mission statement, as
14 updated by the FDA Modernization Act. Regarding food, the
15 FDA mission used quite definitive language, quote:
16 "Protect the public health by insuring that foods are
17 safe." It does not use the language of reasonable
18 assurance, as in the case of, for example, devices
19 intended for human use. This suggest an extremely high
20 bar in terms of acceptable risk. Insure that it is safe.

21 At the same time, it is clear that there's no
22 scientific consensus on the safety of of GE foods.
23 Furthermore, there are no compelling, competing interests
24 here, such as the need to bring medications quickly to
25 market in the case of pharmaceuticals. There's certainly

1 nothing in the FDA mission to elevate developers
2 profitability concerns with insuring safety of food.

3 I therefore submit that FDA's GE food labeling
4 policy should be modified to reflect the highest
5 precautionary regulatory approach as directed by its
6 mission. Insure that our food is safe by requiring
7 rigorous per-product, premarket testing; or, at the very
8 minimum, require appropriate labeling. This is what U.S.
9 consumers are beginning to organize themselves to demand.

10 Thank you.

11 MR. LAKE: Thank you, sir.

12 STATEMENT OF

13 VERNAL GOMES

14 DAIRYMAN/FARMER

15 MR. GOMES: Ladies and gentlemen, I am a dairy
16 farmer, and I am row-crop farmer from the south San
17 Joaquin Valley of California. My brother and I have
18 continued in partnership on our family farm, which was
19 started in 1940 by my father who immigrated to this
20 country. Our operation is located in Tulare, California.
21 We have approximately 2,000 dairy animals, and we grow
22 about 8,000 ton of corn to feed those animals.

23 My first reaction to the term "biotech seed" was
24 not without suspicion. I can understand the feelings of
25 people who react in opposition to such terms — especially

1 when it comes to effecting our food chain. I, nor anyone
2 else, wants to endanger the basic livelihood on this
3 planet. However, I can only say to those who are
4 skeptical: Please take the time to research and
5 understand this wonderful, new and exciting technology,
6 what it's all about.

7 I have planted biotech corn seed on our ranch,
8 and I found it to be one of the most exciting new
9 developments in agriculture. Weed control has always been
10 an age-old problem for farmers and agriculturalists.
11 With biotech seeds, we have been able to control the vast
12 array of problem weeds in our crops, the damage to
13 production which lessened the quality. Biotech crops
14 continue to grow while surrounding competitive weeds die
15 once the field has been sprayed only once with an
16 herbicide. Because of this, we've been able to eliminate
17 several conventional sprayings of herbicides on the same
18 crop. Because of biotechnology, we can eliminate pest
19 control sprayings, also.

20 What a wonderful, wonderful science this is.
21 What a combination. Eliminating herbicide sprayings and
22 insect sprayings, at the same time killing unwanted weeds
23 that damages the quality of our crops.

24 Less farming expense has been realized in our
25 operation because of biotech seeds. Because weed control

1 has been made easier, we have started to eliminate some of
2 the traditional farming practices that we've always done
3 in the past.

4 MR. LAKE: Thank you, sir.

5 [Applause.]

6 STATEMENT OF

7 ERICA PENG

8 BERKELEY FOOD POLICY COUNCIL

9 MS. PENG: Hi! Erica Peng from the Berkeley
10 Food Policy Council.

11 I visited a school garden recently. Proudly and
12 prominently displayed in the very center front was a large
13 banner made by students in the kindergarten through fifth
14 grade. On that banner was a list of the principles that
15 they believed important to learn and practice: Respect,
16 patience, understanding, cooperation, honesty,
17 stewardship, sustainability, relationships and laughter.
18 I invite you to ask yourselves, as members of the FDA and
19 as individuals, and I want to look in your eyes as fellow
20 people as I ask you these questions:

21 Are you exercising these principles to the best
22 of your ability as individuals? I believe that, if you
23 are, you will be exercising them as members of the FDA.

24 What has happened to these principles to learn
25 and live by, as recognized by our elementary school

1 students?

2 Would students feel that you are qualified to
3 teach and lead and to be a model for them? And have these
4 principles been exercised in the way that GE foods have
5 been silently introduced into our food supply?

6 I am disturbed, I am disappointed. I'm not
7 surprised, given the revolving door between industry, the
8 USDA, and FDA, but I am appalled and I am offended at the
9 failure to adequately inform the American public with
10 accessible, non-industry information and resources prior
11 to the release of GMOs in the environment and the food
12 supply.

13 Perhaps you personally didn't have access to the
14 information, which points to how you, too, are victims, as
15 we all are, in this process driven by and for industry
16 profits. It is unacceptable that, while debate ensues
17 about appropriate animal testing models, about labeling,
18 about the science, we are losing sight of the central
19 issue, which is our individual rights to know and approve
20 of our food which has been supplanted by industry profits.
21 Growing numbers of people are not satisfied with the way
22 you are fulfilling your role, or not fulfilling your role.

23 On behalf of the Berkeley Food Policy Council, I
24 want to present two resolutions approved by the Berkeley
25 City Council and the Berkeley School, the Board of

1 Education —

2 MR. LAKE: Thank you, ma'am.

3 MS. PENG: — in support of federal legislation
4 to ban GE food and products.

5 MR. LAKE: Thank you, ma'am.

6 [Applause.]

7 STATEMENT OF

8 TERRI COMPOST

9 GARDENER/CONSUMER

10 MS. COMPOST: Hi! My name is Terri Compost, and
11 I am an eater. And I will try to represent the hundreds
12 of people who are outside and who could be at this public
13 hearing had the doors been opened.

14 We want to know, we want to know the effects of
15 genetically altered food on our bodies and the environment
16 before it is commercially grown, before we eat it. This
17 technology is new, it is radical, it will change
18 evolution. We urge caution. It's taken a long time to
19 get here. We can take our time from here. We need a
20 public assessment of the risks involved. It needs to be
21 tested thoroughly and independently.

22 I'm sure you're aware of the millions of dollars
23 that the industry is putting into convincing you that this
24 is safe, and convincing the public this is safe. In fact,
25 there must be a considerable amount of industry money in

1 the pockets of people in this very room — hopefully not
2 yours.

3 With all our collective scientific brain power,
4 we really know very little about the intricacies of
5 genetics, about our — the human body, about ecology. The
6 current FDA policy of not labeling makes tracking any
7 health problem from genetically modified food virtually
8 untraceable. Convenient for companies trying to avoid
9 liability; devastating for the health of the public. We
10 have a right to know.

11 The broken promises of the Green Revolution need
12 historical review. A decision to allow industry to guide
13 biotech could create rather than solve world food
14 tragedies. Please listen to the public. Your ruling will
15 have effects on many generations. We need moratorium
16 until proven safe and immediate labeling of all
17 genetically engineered products.

18 Thank you. Please take your job seriously.

19 MR. LAKE: Thank you, ma'am.

20 [Applause.]

21 STATEMENT OF

22 IGNACIO H, CHAPELA, Ph.D. ASSISTANT PROFESSOR,
23 DEPARTMENT OF ENVIRONMENTAL SCIENCE, POLICY & MANAGEMENT
24 UNIVERSITY OF CALIFORNIA.

25 DR. CHAPELA: My name is Ignacio Chapella. I am

1 assistant professor of Ecology at the University of
2 California, Berkeley.

3 After 20 years of professional life, dedicated
4 to the study of the unseen world of microbes, the base of
5 our sustenance and survival, I must attest to a very
6 primitive understanding of the consequences of the recent
7 manipulations of plant, animal and microbial life in the
8 new agriculture biotechnologies. We know enough only to
9 know that the new genetic engineering methods have
10 definite and potentially enormous risks to the
11 environment. It is in the nature of those manipulations
12 that the changes we introduce into the environment cannot
13 be contained or recalled, as could perhaps be the case for
14 nuclear or chemical pollution. Genetic engineering, in
15 this sense, is perniciously promiscuous and deeply
16 disruptive in the environment.

17 I believe that an enlightened modern
18 understanding of human health recognizes that the
19 connection between environmental and human health is
20 intrinsic and it's inexorable. I have seen a lot of
21 evidence that we are working with an outdated regulatory
22 system that hasn't even started to ask the first questions
23 about these connections and the risks. Denying or
24 dismissing those and other risks can only be the result of
25 ignorance, neglect or willful misrepresentation. And I am

1 alarmed that some of my colleagues have chosen not to
2 represent those risks to the public for the sake of their
3 benefit, or their peace of mind.

4 Many of my colleagues are being forced to strike
5 false agreements with the life sciences companies to allow
6 them access to funds that they consider necessary for
7 their professional survival. These scientists, ladies and
8 gentlemen, my colleagues, your experts, are compromised by
9 these direct links to these companies that have, as their
10 only credo, profit.

11 I believe that we must not continue with the
12 deployment of these enormously risky applications of
13 wonderful technologies while the gatekeepers of the public
14 interest, the regulatory agencies, the universities, are
15 held hostage by profit interests.

16 MR. LAKE: Thank you, sir.

17 DR. CHAPELA: Thank you very much.

18 [Applause.]

19 STATEMENT OF

20 PILAR M. WEISS

21 MS. WEISS: My name is Pilar Weiss. I'm a
22 graduate student at the School of Public Health at
23 UC-Berkeley.

24 Our discussions today have repeatedly referred
25 to an acceptable and complete amount of safety testing for

1 GMOs. This claim is incredibly suspect. Testing has been
2 grossly inadequate in light of its disregard for the
3 precautionary principle. The testing deemed acceptable
4 does not address the long-term effects of this new
5 technology. This is an especially serious issue in light
6 of the many unexplored exposure pathways GMOs have to
7 human health. This includes chronic, long-term exposure
8 to GMOs as they become more and more pervasive in our food
9 supply, as well as secondary and tertiary exposure via
10 processed foods and GMO-fed livestock.

11 The scientific community cannot forget lessons
12 we have learned from previous instances when caution
13 concerning long-term effects was not considered. In
14 California, I remind you of the repercussions of the use
15 of the pesticide DBCP and the gas additives MTBE. In both
16 cases, rapid approval based on short-term risk assessment
17 has left us in a situation where are scrambling to solve
18 wide-based health and ecological problems.

19 The FDA has the responsibility to uphold the
20 precautionary principle with GMO's entrance into our food
21 supply. If not, we are in danger of irreversible damage
22 to human health and the ecosystem. A moratorium on GMOs
23 must be called until long-term testing has been assessed.

24 [Applause.]

25 MR. KIMBRELL: Thank you, ma'am.

1 //

2 STATEMENT OF
3 ELLEN JEFFERDS
4 NATURAL LAW PARTY

5 MS. JEFFERDS: My name is Ellen Jefferds, and
6 I'm running for Congress this next year, here in this
7 Ninth Congressional District, with the Natural Law Party.

8 I find it astounding that genetic engineering
9 proponents claim they have no substantial evidence that GE
10 food and food products could be potentially dangerous. In
11 1989, 37 people died, 1,500 were partially paralyzed,
12 5,000 were temporarily disabled when they ingested
13 tryptophan, which has been produced with the aid of
14 genetically engineered bacteria. Unexpected chemical
15 reactions produce novel toxins in the tryptophan, toxins
16 which would have passed the current substantially
17 equivalent tests, and also tests designed to detect all
18 known toxins.

19 My husband's cousin was one of those who
20 suffered paralysis, a woman in her mid-thirties. Jeannie
21 lost most of her motor functions. Despite undergoing
22 years of intensive daily physical therapy, she still has
23 limited small motor abilities and has lost many years of
24 active living. The settlement of a class action lawsuit
25 against the manufacturer did not alleviate her pain and

